

FINAL CLINICAL STUDY REPORT

Assessment of Smokers' Nicotine Uptake and Urge to Smoke After Use of Smokeless Tobacco Products

Protocol Number: CSD1101

First Subject Enrolled: 31 October 2011

Last Subject Completed: 22 December 2011

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Date of Report: 07 January 2013

GCP Statement: This study was performed in accordance with Good Clinical Practice (GCP), according to the International Conference on Harmonization (ICH) final guideline (May 1996) including the archiving of essential documents. This report was prepared according to the ICH E3 clinical study report guidelines.

Confidentiality Statement

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2. SYNOPSIS

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Study Title: Assessment of Smokers' Nicotine Uptake and Urge to Smoke After Use of Smokeless Tobacco Products		
Principal Investigator: Gregory P. Tarleton, PharmD, MD		
Study Center: Bellomy Research, 4305 Enterprise Drive, Suite E, Winston-Salem, North Carolina, 27106		
Publication (reference): None		
Study Period: Initiation Date (first subject enrolled): 31 October 2011 Completion Date (last subject completed): 22 December 2011		
Study Objectives: The objectives of this study were to assess the following after a 12-hour tobacco and nicotine abstinence: <ul style="list-style-type: none">• Nicotine uptake in blood over a 3-hour period with respect to in-clinic product administration.• Tobacco abstinence symptoms over a 3 -hour period with respect to in-clinic product administration.		
Methodology: This was a single-center, randomized, open-label, crossover study designed to evaluate serum nicotine uptake and tobacco abstinence symptoms following administration of a single unit each of usual brand (UB) cigarettes and (b) r smokeless tobacco products (STPs), including Camel SNUS (b) (4) in current smokers in generally good health. Subjects must have been willing to abstain from all tobacco and nicotine use for at least 12 hours prior to use of one study product at each of five test visits. The total duration of the study from screening to final test visit was approximately 10 weeks. <p>Up to 20 subjects who met all of the inclusion and none of the exclusion criteria at the Screening Visit and check-in of Test Visit 1 were planned for enrollment and randomization. To ensure up to 20 subjects were eligible for enrollment, an additional 20 alternate subjects were asked to complete all study procedures through check-in of Test Visit 1; those not enrolled at Test Visit 1 were discharged from the study.</p> <p>Enrolled subjects smoked one UB cigarette at Test Visit 1. At the end of Test Visit 1, subjects were randomized to the order of the (b) STPs to be administered at Test Visits 2 through 5. Prior to each test visit, expired carbon monoxide (ECO) was measured to confirm smoking abstinence and to determine subject eligibility to undergo visit procedures.</p> <p>During each test visit, serial blood samples were collected for determination of serum nicotine and cotinine concentrations, and subjects completed questionnaires (Mood and Physical Symptoms</p>		

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Scale [MPSS]) to assess tobacco abstinence symptoms. Safety was evaluated based on data collected for adverse events (AEs), physical examinations including oral examinations, clinical laboratory tests, and vital sign measurements.

Number of Subjects (planned and analyzed): Up to 20 subjects were planned for enrollment and randomization to have at least 16 subjects complete the study. Seventeen subjects were enrolled and included in the statistical analyses of nicotine uptake parameters, product ratings, and tobacco abstinence symptoms, and included in the safety sample.

Diagnosis and Main Criteria for Inclusion: Generally healthy males and females between 21 and 55 years of age (inclusive) who self-reported smoking 10 to 30 cigarettes per day for at least 6 months prior to screening.

Study Products:

- Subject-specific UB cigarettes
- Camel SNUS

(b) (4)

Duration of Product Use: Subjects consumed one unit of assigned study product during each of five test visits. Additionally, prior to visits for STP administration, subjects were to sample one unit of the STP to which they were assigned to confirm that product use was acceptable.

CRITERIA FOR EVALUATION

Biomarkers: (b) (4)

(b) (4)

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(b) (4)

Questionnaires:

- **Fagerström Test for Nicotine Dependence (FTND):** estimated the degree of nicotine dependence at screening
- **Mood and Physical Symptoms Scale (MPSS):** assessed tobacco abstinence symptoms at screening and during each test visit (both before and after study product administration)

Expired Carbon Monoxide: Expired carbon monoxide was measured at screening to confirm inhalation of cigarette smoke, and at the start of each test visit to verify smoking abstinence and to determine subject eligibility to undergo study procedures.

Safety: Safety assessments included:

- AEs
- Physical examination, including oral examinations
- Clinical laboratory testing (complete blood count [CBC], comprehensive metabolic profile [CMP], urinalysis, triglycerides, total cholesterol, pregnancy tests)
- Vital sign measurements (blood pressure, pulse, oral body temperature)

Statistical Methods: All data collected per protocol from all randomized subjects with at least one post-baseline assessment were included in the statistical analysis. Any data collected under protocol deviation were included at the Sponsor's discretion.

All subjects who were randomized and had at least one post-baseline assessment were included in the safety sample.

Biomarkers: (b) (4)

(b) (4)

Questionnaires: FTND scores and MPSS ratings at the Screening Visit were provided in listing format and summarized using descriptive statistics. Paired t-tests were used to assess changes in

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tobacco abstinence symptom responses (MPSS items) before vs. after product use for each of the products. P-values and mean differences from pre-product use were presented in summary tables. Plots of mean scores over time were presented by product. Descriptive statistics were also provided for each MPSS item. Raw MPSS data were also presented in listing format.

Expired Carbon Monoxide: Expired carbon monoxide was presented in listing format only.

Safety: All AEs were coded using the Medical Dictionary for Regulatory Activities (MedDRA), Version 14.1. Adverse events were attributed to the last study product received prior to AE occurrence.

Adverse events were summarized by study product, system organ class (SOC), and preferred term. By-subject listings of AEs, including verbatim term, preferred term, type, frequency, severity, relationship to study product, action taken, treatment, onset date and time, and end date and time were also provided. Adverse events leading to study termination were listed by individual subject.

Clinical laboratory tests, vital sign measurements, oral health examination findings, and physical examination findings were provided in listing format only.

RESULTS AND CONCLUSIONS

Biomarker Results: The extent of nicotine uptake as measured by geometric LS mean AUC_{0-180} was approximately 2 to 3 times greater with UB cigarettes ($1051.5 \text{ ng} \times \text{min/mL}$) compared to STPs (361.0 to $547.5 \text{ ng} \times \text{min/mL}$) ($p < 0.0001$ for all comparisons). Baseline-adjusted AUC values suggest that the difference across study products was somewhat more pronounced with an approximately 2.3 to 4 times greater nicotine AUC_{adj} with UB cigarettes ($913.1 \text{ ng} \times \text{min/mL}$) compared with STPs (223.5 to $390.8 \text{ ng} \times \text{min/mL}$) ($p < 0.0001$ for all comparisons).

Among STPs, the extent of nicotine uptake as measured by geometric LS mean AUC_{0-180} was approximately 1.4 to 1.5 times greater with Camel SNUS ($547.5 \text{ ng} \times \text{min/mL}$) compared with STMs (361.0 to $394.6 \text{ ng} \times \text{min/mL}$) ($p < 0.005$ for all comparisons). Baseline-adjusted AUCs indicate that nicotine uptake across STPs was somewhat more pronounced at approximately 1.4 to 1.7 times greater AUC_{adj} with Camel SNUS ($390.8 \text{ ng} \times \text{min/mL}$) compared with STMs (223.5 to $274.1 \text{ ng} \times \text{min/mL}$) ($p < 0.005$ for all comparisons). Statistical comparisons showed that nicotine uptake was similar between STMs ($p > 0.05$ for all AUC comparisons).

The extent of nicotine uptake from STPs relative to UB cigarettes (AUC_{ratio}) ranged from 24.4% to 42.6%. (b) (4)

Geometric LS mean for nicotine C_{max} was approximately 3 to 5 times greater with UB cigarettes (15.6 ng/mL) compared with STPs (3.0 to 4.7 ng/mL) ($p < 0.0001$ for all comparisons). Adjustments of C_{max} ($C_{max(adj)}$) based on pre-existing nicotine prior to product administration suggests that the difference across study products was more pronounced, with an approximately 4 to 7.5 times greater $C_{max(adj)}$ with UB cigarettes (14.2 ng/mL) compared with STPs (1.9 to 3.5 ng/mL) ($p < 0.0001$ for all comparisons).

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(b) (4)



(b) (4)



Cotinine concentrations (geometric LS mean) at time 0 were similar across study products and ranged from 168.9 to 182.1 ng/mL ($p > 0.05$ for all comparisons).

Questionnaire Data: Use of UB cigarettes compared to STPs more often resulted in significant changes in tobacco abstinence symptoms, with significant reductions in feeling anxious, feeling irritable, feeling restless, having poor concentration, and current urge to smoke. The symptom of feeling depressed was not significantly impacted by the study products. Results for feeling hungry were likely confounded because subjects were permitted to eat during test visits after product use.

(b) (4)



Statistically significant changes from baseline in feeling irritable ($p < 0.05$) were observed with UB cigarettes only, with reductions at 15, 30, 45, 60, 90, 150, and 180 min. Small reductions in feeling irritable were noted with STPs, but none were statistically significant.

Slight fluctuations from baseline in feeling restless occurred for all products, but only a decrease with UB cigarettes at 15 min after administration was statistically significant ($p < 0.05$). For all products, nominal decreases were observed during the first 30 to 60 min, followed by increases by 150 min.

(b) (4)



Through 120 min after administration, current urge to smoke was significantly reduced from baseline ($p < 0.05$) with each study product, with the greatest decreases occurring with UB

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cigarettes. At 150 minutes, significant reductions continued with UB cigarettes and STMs, but not with Camel SNUS. (b) (4)

Expired Carbon Monoxide: At the Screening Visit, all subjects had ECO levels within the protocol-defined range for study inclusion (≥ 15 to ≤ 100 ppm). One subject had an ECO level > 12 ppm at Test Visit 2 and a repeat ECO performed 7 days later; the subject was withdrawn from the study due to noncompliance with the protocol. All other subjects were confirmed to have ECO levels ≤ 12 ppm prior to undergoing procedures for each test visit.

Safety Results: The incidence of subjects with at least one AE, regardless of relationship to study product, was greater with concurrent use of STPs (6.3% to 25.0%) compared with UB cigarettes only (0%). Among STPs, Camel SNUS and (b) (4) were temporally associated with the highest incidence of subjects with AEs (25.0% for each product), (b) (4)

No AE resulted in subject discontinuation from the study, and no AE resulted in cessation or interruption of study product. No subject experienced a serious adverse event (SAE) (including death). All AEs were mild in intensity.

The most commonly reported AEs were throat irritation and headache, reported by two subjects each (one subject each in the Camel SNUS (b) (4) for both AEs).

Safety laboratory parameters with the greatest number of subjects experiencing shifts from normal baseline values were hemoglobin and red blood cells. Five subjects had decreases in hemoglobin to or below the lower limit of normal and four subjects had decreases in red blood cells to below the lower limit of normal. One shift in hemoglobin (13.3 g/dL to 10.7 g/dL [female normal range: 12.0-15.0 g/dL]), in a 36-year-old female, was assessed as clinically significant (CS) by the Principal Investigator (PI). The lab abnormality was recorded as anemia and was assessed as mild in severity and unrelated to study product. No other shifts in safety laboratory parameters were considered CS.

Minor fluctuations in blood pressure and heart rate measurements throughout the study were observed. Four subjects had increases or decreases in weight of greater than 5 pounds (range of 5.6 to 10.6 pounds). No changes in vital sign measurement were considered clinically relevant or reported as AEs.

Physical and oral examinations showed no clinically relevant changes or abnormalities following use of study products.

CONCLUSIONS:

- As measured by AUC_{adj} and $T_{max(adj)}$, the extent of nicotine uptake was 2.3 to 4 times greater and the time to maximum nicotine concentration was 3.7 to 6 times shorter with UB cigarettes compared to the STPs.
- The extent of nicotine uptake (based on AUC_{adj}) was 1.4 to 1.7 times greater with Camel SNUS compared to the STMs.
- (b) (4)

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<ul style="list-style-type: none"> • Use of UB cigarettes resulted in a 4 to 7.5 times greater maximum nicotine concentration (based on $C_{\max(\text{adj})}$) compared to STPs. • (b) (4) • (b) (4) • Use of UB cigarettes compared to STPs more often resulted in significant changes in tobacco abstinence symptoms, with significant reductions in feeling anxious, feeling irritable, feeling restless, having poor concentration, and current urge to smoke. • The symptom of feeling depressed was not significantly impacted by the study products. No meaningful conclusion can be made for the symptom of feeling hungry since results were likely confounded because subjects were permitted to eat during test visits after product use. • (b) (4) • The overall incidence of subjects with AEs, regardless of relationship to study product, was greater with concurrent use of STPs (6.3% to 25.0%) compared with UB cigarettes alone (0%). Among STPs, Camel SNUS and STM-1 were temporally associated with the highest incidence of AEs (25.0% for each product), (b) (4) • The most commonly reported AEs were throat irritation and headache, reported by two subjects each (one subject each in the Camel SNUS (b) (4) for both AEs). • One subject experienced a CS decrease in hemoglobin, which was reported as anemia. The AE was assessed as mild in severity and unrelated to study product. • No clinically relevant changes were noted in vital sign measurements, physical examinations, or oral examinations. 		
Date of Report: 07 January 2013		

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4. LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

Abbreviations	Term or Definition
AE	adverse event
ANOVA	analysis of variance
AUC ₀₋₁₈₀	area under the observable concentration-versus-time curve
AUC _{adj}	baseline-adjusted area under the concentration-versus-time curve
AUC _{ratio}	ratio of AUC _{adj} for smokeless products to AUC _{adj} for cigarette
AUC _{adj(STP)}	baseline-adjusted AUC for smokeless tobacco product
AUC _{adj(UB)}	baseline-adjusted AUC for UB cigarette
BLQ	below the limit of quantitation
CAP	College of American Pathologists
CBC	complete blood count
CCD	Comprehensive Clinical Development, Inc.
CFR	Code of Federal Regulations
CLIA	Clinical Laboratory Improvement Amendment
CMP	comprehensive metabolic profile
C _{max}	maximum concentration
C _{max(adj)}	baseline-adjusted maximum concentration
CS	clinically significant
DMP	Data Management Plan
ECO	expired carbon monoxide
EDC	electronic data capture
FDA	Food and Drug Administration
FTND	Fagerström Test for Nicotine Dependence
FTP	File Transfer Protocol
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
HIV	human immunodeficiency virus
ICH	International Conference on Harmonization
ICF	informed consent form
IEC	Independent Ethics Committee
IRB	Institutional Review Board
IV	intravenous
LC-MS/MS	liquid chromatography with tandem mass spectrometry
LFT	liver function test

Abbreviations	Term or Definition
LLOQ	lower limit of quantitation
LS	least squares
MedDRA	Medical Dictionary for Regulatory Activities
MPSS	Mood and Physical Symptoms Scale
NCS	not clinically significant
PI	Principal Investigator
ppm	parts per million
Q ₁	lower quartile or 25 th percentile
Q ₃	upper quartile or 75 th percentile
®	registered trademark
RJRT	R.J. Reynolds Tobacco Company
SAE	serious adverse event
SAP	Statistical Analysis Plan
SD	standard deviation
SOC	system organ class
SOP	standard operating procedure
STM	simplified tobacco material
STP	smokeless tobacco product
T _{max(adj)}	time to baseline-adjusted maximum concentration
TSNA	tobacco-specific nitrosamine
UB	usual brand
ULOQ	upper limit of quantitation
US	United States
WBC	white blood cell
WHO	World Health Organization

5. ETHICS

5.1 Independent Ethics Committee (IEC) or Institutional Review Board (IRB)

Prior to study commencement, the study protocol and the informed consent form (ICF) were reviewed and approved by a duly constituted Institutional Review Board (IRB).

The IRB for this study was Independent IRB, Inc. The IRB Chairperson was Frances Conway, RN. All IRB information is provided in [Appendix 16.1.3.1](#).

5.2 Ethical Conduct of the Study

The study was conducted in accordance with the United States (US) Code of Federal Regulations (CFR) governing Protection of Human Subjects (21 CFR 50), Financial Disclosure by Clinical Investigators (21 CFR 54), and Institutional Review Boards (IRB) (21 CFR 56). As such, the study was designed and monitored in accordance with Good Clinical Practice (GCP) as required by the major regulatory authorities and in accordance with the ethical principles of the Declaration of Helsinki.

5.3 Subject Information and Consent

The ICF included all elements required by the International Conference on Harmonization (ICH), GCP, and the US Food and Drug Administration (FDA), as well as applicable local regulatory requirements and adhered to the ethical principles that have their origin in the Declaration of Helsinki.

Prior to undergoing any study procedures, subjects were fully informed about the nature, scope, and possible consequences of the study, and were asked to read, sign, and date the ICF. Each subject received a copy of the signed ICF.

A sample ICF is provided in [Appendix 16.1.3.1](#), and representative written information given to subjects is provided in [Appendix 16.1.3.2](#).

6. INVESTIGATORS AND STUDY ADMINISTRATIVE STRUCTURE

This was a single-center study that was conducted at Bellomy Research, a clinical study center located in Winston-Salem, North Carolina. The Principal Investigator (PI) was Gregory P. Tarleton, PharmD, MD; his qualifications are listed in [Appendix 16.1.4](#).

The following responsibilities were delegated to Comprehensive Clinical Development, Inc. (CCD), a clinical research organization with headquarters in Miramar, Florida:

- Protocol development and review and preparation of the clinical study report;
- Data management with regards to review of the electronic source records, testing the electronic source, serious adverse event (SAE) reconciliation, review of edit check programming, managing data queries, preparing the Data Management Plan (DMP), managing data transfers, coding, and data cleaning;
- Biostatistics and statistical programming with regards to generation of the randomization schedule, production of the SAS data sets, and statistical analysis; and
- Project management with regards to maintaining project timelines and arranging regular conference calls between the CCD project team and Sponsor team.

Clinical Trials of America, a clinical trials organization with an office located in Winston-Salem, North Carolina, provided research associates and phlebotomists for the clinical phase of the study.

Clinical Ink, an electronic source records vendor located in Winston-Salem, North Carolina, was responsible for developing and deploying the electronic source records, programming edit checks, preparing the user manuals and data entry guidelines, training, managing user access, storing the electronic records, and overall administration of the electronic source. The clinical database was exported from Clinical Ink to CCD, and Clinical Ink confirmed that the exported database was clean prior to CCD producing final datasets.

All samples for safety laboratory testing were analyzed by Solstas Lab Partners, a laboratory in Greensboro, North Carolina, in accordance with College of American Pathologists (CAP) and Clinical Laboratory Improvement Amendment (CLIA) guidelines. Copies of the CAP and CLIA certificates are provided in [Appendix 16.1.10](#).

Bioanalytical laboratory assessments were performed by Celerion, a Good Laboratory Practice (GLP)-certified laboratory located in Lincoln, Nebraska.

The study was monitored by Phyllis Layfield, BS, of Trio Clinical Research, LLC located in Raleigh, North Carolina.

Contact information for the study site, CCD, Clinical Ink, the safety and bioanalytical laboratories, and study monitor are provided in [Appendix 16.1.4](#).

7. INTRODUCTION

The tobacco control community unanimously supports advising current smokers to quit smoking and never smokers not to start smoking. Some public health officials support the use of smokeless tobacco products (STPs) as an alternative strategy to abstinence for smokers who cannot quit or are unwilling to quit smoking (Stratton *et al.*, 2001). STPs provide an alternative that eliminates exposure to certain combustion toxicants in cigarette smoke, such as carbon monoxide. Additionally, some STPs contain lower levels of tobacco-specific nitrosamines (TSNAs) compared to more traditional STPs. In a 2007 study by Hatsukami *et al.*, the dissolvable tobacco pellet Ariva[®] contained the lowest level of TSNAs of the products tested.

Swedish snus, a moist STP, has relatively low levels of many toxicants compared to cigarette smoke. Results from studies of Scandinavian smokeless tobacco (i.e., snus) users indicated no increased risk of oropharyngeal, larynx, stomach, bladder, kidney, lung, or overall cancer compared with non-users (Lee and Hamling, 2009).

A review of health risks of cigarette smoking compared to Swedish snus suggested the risks for lung, oral, and gastric cancer, and cardiovascular diseases associated with Swedish snus use are lower than those associated with smoking (Roth *et al.*, 2005). An expert panel evaluating the relative risks of low nitrosamine-containing STPs (e.g., snus) compared with cigarette smoking estimated the risk of these smokeless products to be 5 to 10% of that of the health risks from smoking (Levy *et al.*, 2004).

R.J. Reynolds Tobacco Company (RJRT) recently introduced Camel SNUS into the US market. Camel SNUS, designed and manufactured similarly to Swedish snus, has relatively low levels of many tobacco constituents that are considered by some health professionals to potentially cause harm. The use of snus would offer less exposure to those constituents than cigarette smoking.

(b) (4)



Some scientists have suggested that STPs must suppress smoking abstinence symptoms to be a successful alternative to cigarettes (Cobb *et al.*, 2009). Without adequate suppression, smokers may not continue to use reduced toxicant products and consequently may resume exclusive or near-exclusive smoking. Smoking abstinence symptoms include, but are not limited to, restlessness, irritability, anxiety, impaired concentration, depression, increased appetite, and craving to smoke (Benowitz, 1996). Several validated questionnaires exist to assess tobacco consumers' perception of these symptoms after a period of tobacco

abstinence (Hughes and Hatsukami, 1986; Welsch *et al.*, 1999; Shiffman *et al.*, 2000; West and Hajek, 2004; Etter, 2005). A decrease in a smoker's blood nicotine concentration is one factor that contributes to smoking abstinence symptoms.

Ariva was previously shown to partially suppress tobacco abstinence symptoms in smokers following overnight tobacco abstinence (Blank *et al.*, 2008; Cobb *et al.*, 2009; Kotlyar *et al.*, 2007). However, symptoms were suppressed significantly less than after smoking a cigarette, even a cigarette containing very low levels of nicotine. The same studies showed that plasma nicotine levels did not significantly increase above baseline following use of one Ariva pellet. Although the effects of using Ariva were not equal to smoking in those studies, subjects in a different study preferred Ariva over a medicinal nicotine lozenge to assist smoking cessation (Mendoza-Baumgart *et al.*, 2007).

This study examined the use of Camel SNUS and (b) (4) in smokers after a 12-hour tobacco and nicotine abstinence period. Changes in nicotine exposure and tobacco abstinence symptoms following in-clinic administration of one unit of the four different STPs or in-clinic smoking of one usual brand (UB) cigarette were evaluated.

8. STUDY OBJECTIVES

The objectives of this study were to assess the following after a 12-hour tobacco and nicotine abstinence:

- Nicotine uptake in blood over a 3-hour period with respect to in-clinic product administration.
- Tobacco abstinence symptoms over a 3-hour period with respect to in-clinic product administration.

9. INVESTIGATIONAL PLAN

9.1 Overall Study Design and Plan: Description

This was a single-center, randomized, open-label, crossover study designed to evaluate serum nicotine uptake and tobacco abstinence symptoms following administration of a single unit each of UB cigarettes and (b) (4) different STPs, including Camel SNUS (b) (4) (b) (4) in up to 20 current smokers in generally good health.

The total duration of study participation from screening to final visit was approximately 10 weeks. Following the Screening Visit, eligible subjects returned to the study clinic to check in for Test Visit 1. Those who met all of the inclusion and none of the exclusion criteria were enrolled and randomized to the order of the four STPs. Enrolled subjects returned for four subsequent test visits, with 7 to 18 days between visits.

Enrolled subjects smoked one UB cigarette at Test Visit 1, followed by administration of one unit of STP at each of four subsequent test visits. Subjects were required to abstain from all tobacco or nicotine products for at least 12 hours prior to each study product (UB cigarette and STPs) administration.

The overall study design is presented in Figure 1.

(b) (4)



Figure 1: Overall Study Design

To ensure up to 20 subjects were eligible for enrollment, up to an additional 20 alternate subjects were asked to complete all study procedures through check-in of Test Visit 1; those not enrolled at Test Visit 1 were discharged from the study.

Prior to each test visit, expired carbon monoxide (ECO) was measured to confirm smoking abstinence and to determine subject eligibility to undergo visit procedures.

At each test visit, serial blood samples were collected for determination of serum nicotine and cotinine concentrations and subjects completed questionnaires to assess tobacco abstinence symptoms (Mood and Physical Symptoms Scale [MPSS]; copy provided in [Appendix 16.1.3.2](#)).

Safety was evaluated based on data collected for adverse events (AEs), physical examinations including brief oral examinations, clinical laboratory tests, and vital sign measurements.

The schedule of study assessments is depicted in [Table 1](#).

The clinical study protocol and sample data collection forms used for the study are provided in [Appendices 16.1.1](#) and [16.1.2](#), respectively.

9.2 Discussion of Study Design, Including the Choice of Control Groups

This was a single-site, randomized, open-label, crossover study designed to assess nicotine uptake and tobacco abstinence symptoms experienced by subjects following in-clinic administration of a single UB cigarette, one Camel SNUS 600 mg pouch (Frost), (b) (4) (b) (4) after a 12-hour tobacco and nicotine abstinence period.

Usual brand cigarettes were included for comparison because all subjects were current smokers and the use of STPs may be considered an alternative to smoking cigarettes.

A crossover design was chosen to minimize variability and the number of subjects needed for evaluation. A 7- to 18-day period between study product administrations was chosen to allow adequate time for rescheduling of test visits, if required.

By necessity, this study was unblinded due to the different visual appearances of some study products.

9.3 Selection of Study Population

9.3.1 Inclusion Criteria

Each subject was required to meet the following criteria to be included in the study:

1. Able to comprehend and willing to sign an ICF.
2. Able to read, comprehend, and complete questionnaires in English.
3. Male or female, age 21 to 55 years, inclusive.

4. Generally healthy based on screening assessments, as judged by the PI.
5. Primary tobacco use was smoking cigarettes.
6. Smoked combustible, filtered cigarettes, 83 mm to 100 mm length, menthol or non-menthol.
7. Self-reported daily use of 10 to 30 cigarettes at the Screening Visit.
8. Willing to abstain from tobacco and nicotine use for at least 12 hours prior to each study product administration.
9. Females were willing to use a form of contraception acceptable to the PI from the time of signing consent until study discharge or were surgically sterile for at least 90 days prior to enrollment.

9.3.2 Exclusion Criteria

Subjects who met any of the following conditions were excluded from the study:

1. Postponed a decision to quit smoking (defined as planning a quit attempt within a month of the Screening Visit) to participate in this study.
2. Employed by a tobacco company, a sub-contractor of a tobacco company, or handled tobacco as part of their job.
3. Current oral lesion(s) at the Screening Visit.
4. A history of clinically significant (CS) heart disease, kidney disease, asthma or any other lung disease, diabetes, liver disease, neurological disease, or psychiatric disorder, as determined by the PI.
5. Self-reported human immunodeficiency virus (HIV), Hepatitis B, or Hepatitis C infection.
6. Current diagnosis of peptic ulcers or irritable bowel syndrome at the Screening Visit.
7. Uncontrolled hypertension defined as a systolic blood pressure of ≥ 200 mmHg or a diastolic blood pressure of ≥ 100 mmHg.
8. Hemophilia or any other bleeding disorders.
9. Clotting disorders with concomitant use of anticoagulants (see [Section 9.4.7](#)).
10. Gave a whole blood donation within 8 weeks (56 days) prior to the Screening Visit.
11. Weighed < 110 pounds.
12. Poor peripheral venous access (at Screening Visit or Test Visit 1).
13. Hemoglobin level was < 12.5 g/dL at the Screening Visit.
14. Elevated liver function test (LFT) results > 2 times the upper limits of normal on the clinical laboratory tests obtained at the Screening Visit.
15. Serum creatinine level > 1.6 mg/dL on the clinical laboratory tests obtained at the Screening Visit.
16. Any laboratory value (on clinical laboratory tests obtained at the Screening Visit) outside the laboratory reference range, considered by the PI to be CS.
17. ECO level was < 15 parts per million (ppm) or > 100 ppm at the Screening Visit, measured between 12 p.m. and 6 p.m.

18. ECO level was > 12 ppm at check-in of Test Visit 1.
19. Use of cigars or electronic cigarette devices within 30 days prior to the Screening Visit.
20. Use of any type of smokeless tobacco or non-tobacco nicotine-containing product(s) within 30 days of the Screening Visit.
21. Use of illegal substances within 30 days of the Screening Visit
22. Use of any medication or supplement that aids smoking cessation, including varenicline (Chantix[®]) and bupropion (Wellbutrin[®], Zyban[®]), within 30 days of the Screening Visit.
23. Use of lobelia extract within 30 days of the Screening Visit.
24. Self-reported a history of illegal intravenous (IV) drug use.
25. Self-reported drinking more than 14 servings of alcoholic beverages per week (1 serving = 12 oz of beer, 6 oz of wine, or 1 oz of liquor).
26. A positive urine drug screen without disclosure of corresponding prescribed concomitant medication(s), at the Screening Visit or check-in at Test Visit 1.
27. Females with a positive urine pregnancy test.
28. Females that gave birth within the past 12 months prior to the Screening Visit or were currently breastfeeding.
29. Females \geq 35 years of age currently using systemic, estrogen-containing contraception or hormone replacement therapy.
30. Deemed by the PI to be unsuitable for the study due to a medical condition, disease, concomitant medication or any other reason not previously listed that in the opinion of the PI made the subject unsuitable in this clinical trial.

9.3.3 Subject Withdrawal

Subjects were informed that they had the right to withdraw from the study at any time and for any reason. The PI could withdraw a subject from the study for any of the following reasons:

- Change in status with respect to an inclusion/exclusion criterion that was clinically relevant and/or could affect subject safety;
- Non-compliance with protocol requirements;
- AE(s);
- Pregnancy;
- Inability to communicate and/or unwillingness to cooperate with the PI; or
- Other (the reason was specified).

In the event that a subject's study participation was terminated (voluntarily or by the PI) after completion of Test Visit 1, the subject was asked to return for a standard physical examination (to include clinical laboratory tests) as soon as convenient, but no later than 15 days following notification of withdrawal from the study.

The date of subject withdrawal and the reason for discontinuation were recorded on source documents.

9.4 Study Products

9.4.1 Study Products Administered

Subjects were administered a single unit of each of the following study products at test visits:

- Subjects' self-selected UB cigarettes
- Camel SNUS

(b) (4)



Additionally, at the conclusion of Test Visits 1-4, subjects were required to sample one unit of the STP to which they were randomly assigned for the next test visit (see [Section 9.4.5](#)).

Excluding the 12-hour tobacco and nicotine abstinence period prior to each test visit, subjects were permitted to smoke their UB cigarettes *ad libitum* during the course of the study. Subjects recorded UB cigarette use between test visits on Cigarette Use Logs (provided in [Appendix 16.1.3.2](#)) that were distributed at the Screening Visit and at Test Visits 1-4. Subjects were instructed to record the number of UB cigarettes smoked per day and the time their last cigarette was extinguished the evening before each test visit.

9.4.2 Identity of Study Product(s)

9.4.2.1 Usual Brand Cigarettes

Usual brand cigarettes provided and consumed by subjects at Test Visit 1 were confirmed as the same UB cigarettes documented at the Screening Visits. All UB cigarettes were combustible, filtered cigarettes 83 mm to 100 mm in length and menthol or non-menthol.

9.4.2.2 Camel SNUS

Camel SNUS is a pouched, moist snuff product composed of pasteurized tobacco with a low sodium and moisture content, making it spit-free. It is manufactured by RJRT and is commercially available. The Frost variety (600 mg pouch) was administered in this study.

The lot number for Camel SNUS was OT20396; a listing of subjects who received Camel SNUS is provided in [Appendix 16.1.6](#).

9.4.2.3

(b) (4)



(b) (4)



(b) (4)

(b) (4)

[Appendix 16.1.6.](#)

9.4.3 Method of Assigning Subjects to Study Products

All subjects smoked one UB cigarette at Test Visit 1. At the end of Test Visit 1, subjects were randomized to the order of the (b) (4) STPs to be administered at Test Visits 2 through 5. Randomization to the order of STPs was based on a Williams Design.

The randomization schedule is provided in [Appendix 16.1.7.](#)

9.4.4 Study Product Administration: Frequency, Timing, and Instructions

At Test Visit 1, subjects smoked one UB cigarette and at Test Visits 2-5, subjects consumed one unit of the assigned STP, with 7 to 18 days between each study product administration.

During test visits, study products were administered following a 12-hour abstinence period from all tobacco and nicotine products. The 12-hour abstinence allowed for serum nicotine levels resulting from pre-abstention tobacco use to decline to near zero so that nicotine uptake from the product being tested could be evaluated with minimal adjustment for background nicotine.

Subjects were to comply with the following instructions for in-clinic administration of STPs:

Smokeless Camel SNUS use instructions:

- Place the pouch between your upper or lower lip and gum.
- Leave the pouch in place for a minimum of 15 minutes.
- Do NOT leave the pouch in place for more than 30 minutes.
- Occasionally move the pouch to a different location between your upper or lower lip and gum (suggested, but not required).
- Do not chew the product.
- Do not spit during or after use (during the test visit).
- Do not eat or drink while using the product.
- Do not swallow the product.

(b) (4)



9.4.5 Study Product Sampling

At the conclusion of Test Visits 1-4, subjects were required to sample one unit of the STP to which they were randomly assigned for the next test visit. Subjects were requested to use the smokeless product according to the product use instructions provided in [Section 9.4.4](#). After sampling, subjects were asked to reconfirm their consent to participate in the study.

9.4.6 Blinding

By necessity, this study was unblinded due to the different visual appearances of some study products.

9.4.7 Prior and Concomitant Therapy

From the time of providing informed consent through study completion (or early termination), subjects were not permitted to use any tobacco- or nicotine-containing products other than UB cigarettes or study STPs.

Use of the following medications excluded potential subjects from study participation and was prohibited during the course of the study:

- All nicotine replacement products
- Varenicline (Chantix[®])
- Bupropion (Wellbutrin[®], Zyban[®])
- Lobelia extract
- In female subjects ≥ 35 years of age, use of systemic, estrogen-containing contraception or hormone replacement therapy
- Anticoagulants including, but not limited to:
 - Clopidogrel (Plavix[®])

- Warfarin (Coumadin[®], Jantoven[®])
- Aspirin (> 325 mg/day)

Concomitant medications to treat chronic health conditions were permitted during study participation provided that the medications were not exclusionary and that doses were stable (as determined by the PI).

All medications (including over-the-counter, vitamin/mineral supplements, other dietary supplements and herbal supplements) taken by subjects from up to 30 days prior to the Screening Visit through study completion (or early termination) were recorded on source documents using a Lexi-Comp medication database and coded using the World Health Organization (WHO) Drug Dictionary, Version 111 (March 2011).

9.4.8 Study Product Compliance

The administration and consumption of study products during test visits occurred under the direct supervision of study site staff to ensure that all units of study products were consumed in accordance with the protocol. Subject compliance with consumption of each STM was confirmed by a visual mouth check at the end of product administration. Compliance with use of Camel SNUS was confirmed by collection (and subsequent disposal) of used snus pouches by study site staff. The duration of study product use at each test visit was documented.

9.5 Study Endpoints and Safety Measurements

9.5.1 Biomarkers, Questionnaires, Expired Carbon Monoxide, and Safety Measurements Assessed and Flow Chart

9.5.1.1 Biomarkers

(b) (4)



(b) (4)



9.5.1.2 Questionnaires

Fagerström Test for Nicotine Dependence (FTND)

The FTND ([Heatherton *et al.*, 1991](#)) was administered at the Screening Visit. The FTND is a validated instrument consisting of six items that provides a short, reliable, self-reported measure of nicotine dependence related to cigarette smoking (reviewed in [de Meneses-Gaya *et al.*, 2009](#)). A copy of the FTND is provided in [Appendix 16.1.3.2](#).

Mood and Physical Symptoms Scale (MPSS)

The MPSS ([West *et al.*, 1984](#); [West and Hajek, 2004](#)) was administered at the Screening Visit and 10 times during each test visit to assess tobacco abstinence symptoms. At each test visit, the MPSS was administered prior to study product administration and at 5, 15, 30, 45, 60, 90, 120, 150, and 180 minutes following the start time of in-clinic study product administration. At the 5-, 15-, 30-, and 45-minute time points, subjects were to start the MPSS within 1 minute following the scheduled administration time point. At the 60-, 90-, and 120-minute time points, subjects were to start the MPSS within 2 minutes following the scheduled administration time point. At the 150- and 180-minute time points, subjects were to start the MPSS within 5 minutes following the scheduled administration time point. A copy of the MPSS is provided in [Appendix 16.1.3.2](#).

Exit Questionnaire

An Exit Questionnaire was administered at Test Visit 5, just prior to study discharge. Subjects were asked about their experiences during study participation. Results were used to improve site performance and are not reported in this document. A copy of the Exit Questionnaire is provided in [Appendix 16.1.3.2](#).

9.5.1.3 Expired Carbon Monoxide

Expired carbon monoxide was measured at the Screening Visit to confirm the subjects “routinely” inhaled cigarette smoke, and at the start of each test visit to verify smoking abstinence and to determine subject eligibility to undergo study procedures.

At screening, subjects were required to have an afternoon (between 12 and 6 p.m.) ECO of ≥ 15 ppm and ≤ 100 ppm to be considered for study participation.

Subjects were required to have an ECO \leq 12 ppm to participate in each test visit. Subjects with an ECO $>$ 12 ppm at Test Visit 1 were not eligible for study enrollment. Enrolled subjects with an ECO $>$ 12 ppm at Test Visits 2, 3, 4, or 5 were not eligible to participate in the test visit procedures that day, but were given the opportunity to reschedule the test visit within the scheduling window. Any subject with an ECO $>$ 12 ppm at any 2 test visits after Test Visit 1 was withdrawn from the study.

Additional ECO measurements were performed at the PI's discretion.

9.5.1.4 Safety Measurements

Adverse Events

Adverse events were defined as any untoward medical occurrence experienced by a subject throughout the course of the study following subject enrollment (at Test Visit 1), whether or not considered study product-related by the PI. Any untoward medical occurrence experienced by a subject prior to study enrollment was recorded as an intercurrent illness and was considered an update in the subject's medical history.

Adverse events were considered as any unfavorable and unintended sign (e.g., abnormal laboratory finding), symptom, or disease, with any judgment about causality.

All AEs, whether volunteered, elicited, or noted on physical examination, were recorded throughout the study on source documents and coded using the Medical Dictionary for Regulatory Activities (MedDRA), Version 14.1. M PSS questionnaire responses were not used to evaluate or capture AEs.

The severity of an AE was categorized based on the following criteria:

- **MILD** = experience was minor and did not cause significant discomfort to subject or change in activities of daily living; subject was aware of symptoms, but symptoms were easily tolerated;
- **MODERATE** = experience was an inconvenience or concern to the subject and caused interference with activities of daily living, but the subject was able to continue with activities of daily living;
- **SEVERE** = experience significantly interfered with activities of daily living, and the subject was incapacitated and/or unable to continue with activities of daily living.
- **LIFE-THREATENING** = experience placed the subject at immediate risk of death.
- **DEATH** = experience resulted in the subject's death.

The relationship between each AE and the study product was determined by the PI according to the following criteria:

- **DEFINITE** = an AE that followed a reasonable temporal sequence from use of the study product (including the course following discontinued use of the study

material), followed a known or hypothesized cause-effect relationship, and (if appropriate) satisfied the following:

- positive results obtained in study product sensitivity tests;
- toxic level of the study product present in blood or other body fluids.
- **PROBABLE** = an AE that followed a reasonable temporal sequence from use of the study product (including the course following discontinued use of the study product) and that could be excluded as being possibly caused by other factors, such as underlying disease, complications, concomitant medications, or concurrent treatment.
- **POSSIBLE** = an AE that followed a reasonable temporal sequence from the use of the study product (including the course following discontinued use of the study product) and that could not be excluded as being possibly caused by the study product (e.g., existence of similar reports attributed to the suspected study product and/or its analogues; reactions attributable to the pharmacological effect of the study product), although other factors such as underlying disease, complications, concomitant medications, or concurrent treatment were presumable.
- **UNLIKELY** = an AE with an improbable temporal sequence from the use of the study product and could be reasonably explained by other factors, such as underlying disease, complications, concomitant medications, or concurrent treatment.
- **UNRELATED** = an AE that did not follow a reasonable temporal sequence from use of the study product and that could be reasonably explained by other factors, including underlying disease, complications, concomitant medications, or concurrent treatment.

An SAE was defined as any AE or suspected adverse reaction that resulted in any of the following outcomes:

- Death;
- A life-threatening adverse study product experience (i.e., placed the subject, in the view of the PI, at immediate risk of death);
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect;
- An important medical event that may have required medical or surgical intervention to prevent one the above outcomes.

Important medical events that did not result in death, were not life threatening, or did not require hospitalization were considered SAEs when, based upon appropriate medical

judgment, they jeopardized the subject and required medical or surgical intervention to prevent one of the outcomes listed in this definition.

Subjects with unresolved or new AEs at the final visit (or early termination) were followed by the PI until the AE was stabilized. Stabilization occurred when the PI did not expect further improvement or worsening of the AE. The PI reported any follow-up information considered CS to the Sponsor.

Physical Examination Including Oral Examination

Standard physical examinations, including an oral examination, were performed by the PI at the Screening Visit and at the end of Test Visit 5 (or early termination). The physical examination included, but was not limited to: heart, lungs, abdomen, skin, ear, nose, throat, and neck. The oral examination consisted of an oral soft tissue examination for evidence of leukoplakia, other oral keratosis, or oral lesions.

Clinical Laboratory Tests

Clinical laboratory tests that were performed at the Screening Visit and at Test Visit 5 (or early termination) included the following:

- **Complete blood count (CBC):** hematocrit, hemoglobin, mean corpuscular hemoglobin, mean corpuscular hemoglobin concentration, mean corpuscular volume, platelet count, red blood cell distribution width, red blood cell count, and white blood cell count
- **Comprehensive metabolic profile (CMP):** albumin, alkaline phosphatase, alanine aminotransferase, aspartate aminotransferase, blood urea nitrogen, calcium, chloride, carbon dioxide, creatinine, glucose, potassium, sodium, total bilirubin, and total protein
- **Urinalysis (macroscopic):** urine color and appearance, urine pH, urine specific gravity, urine bilirubin, urine glucose, urine ketones, urine leukocytes, urine nitrite, urine protein, occult blood, and urobilinogen
- **Triglycerides**
- **Total Cholesterol**

Clinical laboratory results that were outside the normal ranges listed were assessed by the PI as clinically significant (CS) or not clinically significant (NCS). All CS results were exclusionary for participation in the study.

- Hemoglobin levels must have been ≥ 12.5 g/dL at the Screening Visit for subjects to be eligible for enrollment. Clinically significant hemoglobin levels at Test Visit 5 (or early termination) were recorded as AEs.
- Subjects with an LFT > 2 times the upper limit of normal range were not enrolled in the study.
- Subjects with a serum creatinine level > 1.6 mg/dL were not enrolled in the study.

A urine drug screen was performed at the Screening Visit and Test Visit 1. Subjects with positive urine drug screens without disclosure of corresponding prescribed concomitant medication(s) were not enrolled.

Urine pregnancy tests were performed at the Screening Visit and at each test visit for all females. Females must have tested negative for pregnancy to be eligible for enrollment and at each subsequent test visit to continue in the study.

Vital Signs

Blood pressure was measured (after subjects were seated for at least 5 minutes) at the Screening Visit and check-in for Test Visits 1 through 5 (or early termination). Systolic and diastolic blood pressures must have been < 200 mmHg and < 100 mmHg, respectively, to be eligible for enrollment and at each subsequent test visit to continue in the study. Additional blood pressure measurements could have been taken at the discretion of the PI.

Pulse rate (after subjects were seated for at least 5 minutes) and oral body temperature were measured at the Screening Visit, Test Visit 1, and at the end of Test Visit 5 (or early termination).

9.5.1.5 Schedule of Events

The schedule of events for all study visits is presented in [Table 1](#).

Table 1: Schedule of Events

Evaluation	Screening Visit (up to 30 days)	Test Visit 1	Test Visit 2	Test Visit 3	Test Visit 4	Test Visit 5
Informed Consent	X					
Inclusion/Exclusion Criteria	X	X				
Demographics/Height/Weight	X					
Blood Pressure ^a	X	X	X	X	X	X
Pulse Rate ^a	X	X				X
Body Temperature (oral)	X	X				X
Urine Drug Screen	X	X				
Urine Pregnancy Screen (females only)	X	X	X	X	X	X
Clinical Laboratory Tests ^b	X					X
Physical Examination	X					X
Oral Examination	X					X
Medical History	X	X ^c	X ^c	X ^c	X ^c	X ^c
Documented Contraception Method (females only)	X					
Fagerström Test for Nicotine Dependence	X					
Expired Carbon Monoxide	X ^d	X	X	X	X	X
UB Cigarette Pack (photocopied and recorded description information)	X					
Recorded Time of Last Cigarette Prior to Visit ^e	X	X	X	X	X	X
Tobacco/Nicotine Abstinence Instructions	X	X	X	X	X	
Cigarette Use Log ^f	X	X	X	X	X	X
Enrollment & Randomization		X ^g				
IV Catheter ^h		X	X	X	X	X
Confirmed UB Cigarette		X	X	X	X	X
Collected one UB Cigarette		X				

Evaluation	Screening Visit (up to 30 days)	Test Visit 1	Test Visit 2	Test Visit 3	Test Visit 4	Test Visit 5
Assessed Compliance with Tobacco/Nicotine Product Restrictions		X	X	X	X	X
Study Product Administration/ Instructions for STP Use/ Record Duration of Use		X	X	X	X	X
Nicotine/Cotinine Blood Samples ⁱ		X	X	X	X	X
Mood and Physical Symptoms Scale ^j	X	X	X	X	X	X
Adverse Event Assessment		X	X	X	X	X
Concomitant Medication Assessment	X	X	X	X	X	X
Sampled Assigned Study Product for Next Visit/ Instructions for STP Use		X	X	X	X	
Exit Questionnaire						X
Discharged Subject from Study						X

a. Blood pressure and pulse were obtained after subject had remained seated for at least 5 minutes.

b. Included complete blood count (CBC), comprehensive metabolic profile (CMP), urinalysis, triglycerides, and total cholesterol.

c. Findings from medical history documented at screening were updated.

d. ECO level was obtained between 12 p.m. and 6 p.m.

e. At the Screening Visit, the estimated time was recorded; at test visits, the actual time from the Cigarette Use Log was recorded.

f. Blank logs were dispensed at the Screening Visit and Test Visits 1, 2, 3, and 4. Completed logs were collected at Test Visits 1, 2, 3, 4, and 5.

g. Subjects who were not enrolled were discharged and their previously collected UB cigarette was returned.

h. Catheter was inserted prior to administration of study product, and was removed after collection of scheduled blood samples.

i. Samples were collected at pre-0, 0, 3, 5, 7.5, 10, 15, 20, 30, 45, 60, 75, 90, 120, 150, and 180 minutes with respect to in-clinic study product administration.

j. At each test visit, questionnaire was administered prior to attempting catheter placement and at 5, 15, 30, 45, 60, 90, 120, 150, and 180 minutes with respect to in-clinic study product administration.

9.5.2 Appropriateness of Measurements

The sampling schedule for assessment of serum nicotine concentrations and the subsequent calculation of uptake parameters for nicotine were deemed appropriate to characterize nicotine uptake that resulted from use of a single unit of study product.

The assessment of serum cotinine concentrations at time zero was deemed appropriate to determine longer-term changes in tobacco use prior to each test visit.

The FTND is widely used and is considered a standard and reliable instrument for assessment of nicotine dependence.

The MPSS is considered a reliable measure of tobacco abstinence symptoms.

Measurement of ECO levels has been demonstrated to provide a more accurate characterization of smoking status compared to self-reported cigarette use (Vogt *et al.*, 1977).

The safety assessments represent standard measures of subject safety and well-being during clinical studies.

9.5.3 Biomarker Concentration Measurements

(b) (4)



9.5.4 Biomarker Evaluations

(b) (4)



(b) (4)

Table 2: Analytical Method for Determination of Nicotine and Cotinine Concentrations in Serum Samples

Biomarker	Matrix	Method	LLOQ	ULOQ
Nicotine/Cotinine				
Nicotine	Serum	LC-MS/MS ^a	0.5 ng/mL	50.0 ng/mL
Cotinine	Serum	LC-MS/MS ^a	1.0 ng/mL	200 ng/mL

Source: Bioanalytical Report ([Appendix 16.5](#))

LLOQ=lower limit of quantitation; ULOQ=upper limit of quantitation; LC-MS/MS=liquid chromatography with tandem mass spectrometry

a. Samples were analyzed at Celerion, Lincoln, Nebraska.

9.6 Data Quality Assurance

The PI attests that the clinical portion of this study was performed in compliance with the study site SOPs and applicable RJRT Clinical Studies Division SOPs. The SOPs were written based on the principles and requirements of GCP as defined by regulatory agencies' standards and in accordance with the principles enunciated in the Declaration of Helsinki (amended by 59th World Medical Association General Assembly, Seoul, Korea, 2008).

A site initiation visit was held on 13 September 2011 prior to the start of the study. The protocol, study procedures and assessments, study product administration, and GCP were reviewed with the PI, study coordinators, and research associates.

Electronic source records were designed by RJRT and Clinical Ink and reviewed and approved by RJRT to capture and record all protocol-required information and data for each subject. User accounts and passwords were established for all electronic source users after successful completion of an online training course. Electronic source records were completed according to data entry guidelines. The electronic source was programmed with edit checks to identify common data issues, such as missing data, data discrepancies, and out-of-range data. Completed electronic source records were reviewed by the PI (or designee) and the study monitor to confirm accuracy and completeness.

Communication between the Sponsor and study site was maintained by frequent in-person discussions, phone communication, and electronic mail. The study monitor visited the site periodically as outlined in the clinical monitoring plan to ensure the following: compliance with the protocol, adherence to regulatory and ICH/GCP obligations, correct supply and

storage of study products, accurate reporting of AEs, proper source documentation completion, maintenance and retention of study records, and accurate study product accountability. At each monitoring visit, source documents were reviewed for completeness and accuracy.

Clinical laboratory data were faxed from the safety laboratory to the study site and were transcribed to the electronic source forms by site staff, followed by PI review and signature. The study monitor performed 100% review of safety laboratory source data transcriptions. Clinical data from the electronic source records were exported to the study database. Nicotine and cotinine concentration data were transmitted from the bioanalytical laboratory to CCD via a secure File Transfer Protocol (FTP) site and were reconciled by CCD Data Management to ensure data validity and integrity. Reconciliation included manual verification of data (i.e., subject, visit, schedule time) recorded in the database against data reported by the bioanalytical laboratory; any discrepancies were queried. Additionally, any discrepancies discovered during merging of bioanalytical data (merged by subject, visit, and schedule time) for statistical programming were reviewed and resolved.

A Data Management Plan (DMP) was designed for the study and updated on an as-needed basis. The DMP described the data reviews performed by CCD Data Management to ensure quality, consistency, and plausibility of the data. CCD Data Management performed hybrid clinical data monitoring, which was a separate, but similar process compared to monitoring performed at the study site by the study monitor. Hybrid monitoring consisted of full reviews for data errors, data consistency, completeness, identification of derivations/sub-calculations/formulas, and generation of manual queries for each electronic source form. Ongoing data review was also performed by CCD Data Management and included generation, review, and resolution of manual queries; review and resolution of system queries; and management of queries through listing review.

To achieve database lock, a number of steps were taken to ensure that data from all expected subjects were received by accounting for all expected electronic source records and external laboratory data. Following deactivation of the source database and prior to locking of the study database, CCD Data Management performed an additional data review of the last data export from Clinical Ink and all identified data discrepancies were documented and resolved. Other elements of data finalization were also confirmed to have been completed, such as coding of AEs and concomitant medications. An end-of-study quality control review was performed on 10% of all queries processed, selected randomly across the database. Additionally, a 100% quality control review for the accuracy, consistency, and clarity of critical safety variables was completed for all subjects. All data discrepancies were resolved and the database was updated accordingly.

The clean database was closed and locked on 02 August 2012. Upon database lock, data were extracted into SAS datasets and made available for statistical analyses.

Following completion of study conduct, the Sponsor-contracted quality assurance vendor, Quality and Compliance Consulting, Inc., audited the bioanalytical laboratory (Celerion) and

the IRB (Independent IRB, Inc.). Quality and Compliance Consulting also audited this clinical study report. Audit certificates issued by (b) (4) are provided in [Appendix 16.1.8](#).

CCD did not conduct any quality assurance audits.

9.7 Statistical Methods Planned in the Protocol and Determination of Sample Size

Planned statistical analyses as outlined in the Statistical Analysis Plan (SAP) are reported in this section. The SAP was finalized prior to database lock; a copy is provided in [Appendix 16.1.9](#).

9.7.1 Statistical and Analytical Plans

9.7.1.1 General Statistical Considerations

(b) (4)



9.7.1.2 Subject Disposition, Demographics and Background Characteristics, Cigarette Usage, and Concomitant Medications

Subject disposition including the number of subjects enrolled, the number of subjects who completed the study, and the reasons for discontinuation were summarized. Subject disposition was also provided in listing format.

Demographics, number of years smoked, cigarettes per day, FTND scores, and MPSS ratings at the Screening Visit were provided in listing format and summarized using descriptive statistics.

Usual brand descriptor information was summarized using frequency counts and percentages and was also provided in listing format.

Medical history findings, UB cigarette usage data (collected during the study), and concomitant medication usage were presented in listing format only.

9.7.1.3 Biomarkers, Questionnaires, and Other Non-Safety Information

Biomarkers

(b) (4)



(b) (4)



Questionnaires (Mood and Physical Symptoms Scale)

Paired t-tests were used to assess changes in tobacco abstinence symptom responses before vs. after product use for each of the products. P-values and mean differences from pre-product use were presented in summary tables. P lots of mean scores over time were presented by product. Descriptive statistics were also provided for MPSS items at each time point for each product. In addition, raw MPSS data were presented in listing format.

Expired Carbon Monoxide

Expired carbon monoxide was presented in listing format only.

Product Usage Time

Descriptive statistics and a notched boxplot of usage time were produced for each product. Product usage time was also presented in listing format. Study product sampling time was also provided in listing format.

9.7.1.4 Safety Analysis

All AEs were coded using MedDRA, Version 14.1. Adverse events were attributed to the last study product received prior to AE occurrence.

Adverse events were summarized by study product, system organ class (SOC), and preferred term. By-subject listings of AEs, including verbatim term, preferred term, type, frequency, severity, relationship to study product, action taken, treatment, onset date and time, and end date and time were also provided. Adverse events leading to study termination were listed by individual subject.

Clinical laboratory tests, vital sign measurements, oral health examination findings, and physical examination findings were provided in listing format only.

9.7.2 Determination of Sample Size

The sample size was based on existing knowledge and research experience. Based on the requirements of the randomization method (i.e., Williams Design), the target number for completion of this study was a minimum of 16 subjects.

9.8 Changes in the Conduct of the Study or Planned Analyses

9.8.1 Changes in the Conduct of the Study

The original protocol was finalized on 22 July 2011 (Version 1.0). There were no amendments to the protocol.

An administrative letter (dated 24 August 2011) was issued to clarify that mean platelet volume would not be assessed for this study. The PI confirmed that there were no safety concerns related to not assessing mean platelet volume.

The protocol and administrative letter are provided in [Appendix 16.1.1](#).

9.8.2 Changes in the Planned Analyses

After approval of the SAP, it was discovered that one planned listing for study product sampling was inadvertently omitted. The by-subject listing includes the start and stop times for each product sampling along with subject reconfirmation of consent to continue in the study; this listing is provided in Appendix 16.2.5 ([Listing 16.2.5.4](#)).

During review of tables, listings, and figures, it was identified that T_{\max} was based on unadjusted concentrations as outlined in the SAP. However, it was determined by the Sponsor that T_{\max} based on adjusted concentrations (i.e., adjusted C_{\max} or $C_{\max(\text{adj})}$) was more appropriate, and the affected tables, listing, and figures were revised accordingly.

All other analyses were conducted according to the SAP. The SAP is provided in [Appendix 16.1.9](#).

10. STUDY SUBJECTS

10.1 Disposition of Subjects

A tabulation of subject disposition for all randomized subjects is presented in Section 14.1, [Table 14.1.1](#). Disposition for individual subjects is presented in Appendix 16.2.1, [Listing 16.2.1](#).

Of the 17 enrolled and randomized subjects, 16 (94.1%) completed the study and 1 (5.9%) (Subject 07) was withdrawn prematurely because of noncompliance with the protocol (Table 3).

Table 3: Summary of Subject Disposition (All Randomized Subjects)

	All Randomized Subjects (N=17)
Completed the study	16 (94.1%)
Discontinued from the study	1 (5.9%)
Reason for discontinuation:	
Protocol noncompliance	1 (5.9%)

Source: [Table 14.1.1](#)

10.2 Protocol Deviations

The following protocol deviations for enrolled subjects were recorded by study site staff:

- MPSS administered outside of the protocol-defined window:
 - Test Visit 1: Subject 01 (5 min MPSS, 39 sec out of window), Subject 08 (45 min MPSS, 7 sec out of window); Subject 11 (90 min MPSS, 5 min 54 sec out of window)
 - Test Visit 3: Subject 05 (15 min MPSS, 1 min 21 sec out of window), Subject 08 (15 min MPSS, 2 min 3 sec out of window), Subject 14 (120 min MPSS, 6 min 1 sec out of window)
 - Test Visit 5: Subject 02 (30 min MPSS, 21 sec out of window)
- Blood biomarker samples not collected:
 - Test Visit 1: Subject 03 (7.5 and 10 min samples not collected)
 - Test Visit 2: Subject 14 (75 min sample not collected)
 - Test Visit 3: Subject 08 (7.5 min sample not collected due to difficulty with IV catheter)

- Blood biomarker samples collected outside of protocol-defined window:
 - Test Visit 1: Subject 14 (75 min sample, 3 min 40 sec out of window); Subject 11 (90 min sample, 6 min 17 sec out of window)
 - Test Visit 2: Subject 06 (3 min sample, 5 sec out of window; 150 min sample, 12 sec out of window)
 - Test Visit 3: Subject 05 (10 min sample, 2 min 3 sec out of window; 15 min sample, 1 min 27 sec out of window; and 20 min sample, 9 sec out of window), Subject 06 (75 min sample, 18 sec out of window), Subject 14 (120 min sample, 5 min 24 sec out of window)
 - Test Visit 4: Subject 11 (180 min sample, 1 min 58 sec out of window)
- ECO > 12 ppm at test visit:
 - Test Visit 2: Subject 07 (ECO was > 12 ppm and subject was not eligible to participate in Test Visit 2; repeat ECO 7 days later was also > 12 ppm, and subject was withdrawn from study due to protocol noncompliance)
- Timing of IV catheter placement:
 - Test Visit 3: Subject 01 (pre-0 MPSS administered after attempting placement of IV catheter), Subject 03 (IV catheter removed after start time of product sampling)

None of the deviations were considered to have a significant impact on the overall study data or conclusions.

One subject (Subject 12) had unadjusted nicotine concentrations that suggested possible use of smokeless tobacco product(s) during abstinence periods (Appendix 16.2.5, [Listing 16.2.5.1](#)). A protocol deviation was not identified because the subject had ECO levels ≤ 12 ppm at each test visit (implied abstinence from cigarettes), answered “No” to check-in questions (implied no use of non-UB cigarettes, nicotine replacement products, or any tobacco product other than cigarettes), and the subject’s study discharge date preceded receipt of bioanalytical data. The subject was included in analysis of nicotine uptake.

Four subjects had positive urine drug screens (Appendix 16.2.2, [Listing 16.2.2](#)). In three cases, the subjects took a prescribed concomitant medication and per protocol, were permitted to participate in the study. In the fourth case, the subject was positive for opiates, but did not have proof of a prescription at the initial Screening Visit; a repeat urine drug screen 14 days later was negative and the subject was allowed to participate in the study. All other exclusionary tests (urine drug screens and pregnancy tests) were negative.

11. BIOMARKER, QUESTIONNAIRE, AND EXPIRED CARBON MONOXIDE ASSESSMENTS

11.1 Data Sets Analyzed

All available data from all enrolled and randomized subjects (N=17) were included in analyses of nicotine uptake, cotinine at time 0, and tobacco abstinence symptoms.

All 17 enrolled subjects were included in analyses of safety assessments.

11.2 Demographic and Other Baseline Characteristics

A tabular summary of demographic information is presented in Section 14.1, [Table 14.1.2](#). Demographic information is listed by subject in Appendix 16.2.3, [Listing 16.2.3.1](#).

Key demographic data are summarized in Table 4. Eleven (64.7%) subjects were female and six subjects (35.3%) were male. The majority of subjects (16 of 17 subjects; 94.1%) were Caucasian. Mean age of subjects was 36.1 years (range, 25 to 53 years), and mean weight was 181.72 lbs (range, 123.2 to 267.0 lbs).

Table 4: Demographics at Screening (All Randomized Subjects)

Parameter	All Randomized Subjects (N=17)
Gender, n (%)	
Female	11 (64.7%)
Male	6 (35.3%)
Age (years)	
Mean (SD)	36.1 (9.36)
Median	35.0
Min, Max	25, 53
Race, n (%)	
Caucasian	16 (94.1%)
African American	1 (5.9%)
Height (inches)	
Mean (SD)	66.50 (4.370)
Median	65.00
Min, Max	61.0, 74.0
Weight (lbs)	
Mean (SD)	181.72 (48.272)
Median	170.00
Min, Max	123.2, 267.0

Source: Table 14.1.2

SD=standard deviation

Mean baseline scores for MPSS and FTND are provided in Table 5. In general, subjects were not feeling depressed, anxious, irritable, restless, or having poor concentration, but were feeling slightly hungry, and had a slight to moderate urge to smoke. The mean baseline total score for the FTND was 5.0. Since FTND scores can range from a minimum of 0 to a maximum of 10, an average FTND score of 5 indicates a medium level of nicotine dependence.

Table 5: Mood and Physical Symptoms Scores and Fagerström Test for Nicotine Dependence Score at Screening (All Randomized Subjects)

Parameter	All Randomized Subjects (N=17)
Mood and Physical Symptom Scores, Mean (SD)	
Depressed	1.1 (0.24)
Anxious	1.4 (0.61)
Irritable	1.2 (0.53)
Restless	1.3 (0.59)
Hungry	2.2 (0.66)
Poor concentration	1.2 (0.66)
Urge to smoke	1.5 (0.94)
Fagerström Test for Nicotine Dependence, N (%)	
How soon after you wake up do you smoke your first cigarette?	
Within 5 min	5 (29.4%)
6 to 30 min	8 (47.1%)
31 to 60 min	3 (17.6%)
After 60 min	1 (5.9%)
Do you find it difficult to refrain from smoking in places where it is forbidden, e.g. in church, at the library, in cinema, etc.?	
Yes	7 (41.2%)
No	10 (58.8%)
Which cigarette would you hate most to give up?	
The First One in the Morning	8 (47.1%)
Any Other	9 (52.9%)
How many cigarettes per day do you smoke?	
≤ 10	0
11-20	13 (76.5%)
21-30	4 (23.5%)
≥ 31	0
Do you smoke more frequently during the first hours after waking than during the rest of the day?	
Yes	7 (41.2%)

Parameter	All Randomized Subjects (N=17)
No	10 (58.8%)
Do you smoke if you are so ill that you are in bed most of the day?	
Yes	8 (47.1%)
No	9 (52.9%)
FTND Total Score, Mean (SD)	5.0 (2.06)

Source: [Table 14.1.2](#)

SD=standard deviation; FTND=Fagerström Test for Nicotine Dependence

Subjects' UB cigarettes, number of cigarettes typically smoked per day, and the duration of smoking are summarized in Section 14.1, [Table 14.1.3](#) and are listed by subject in Appendix 16.2.3, [Listing 16.2.3.2](#). The most commonly smoked UB cigarette was Camel Menthol Silver (3 of 17 subjects, 17.6%), followed by Marlboro Gold (2 of 17 subjects, 11.8%). The majority of subjects smoked UBs that were 83 mm in length (12 of 17 subjects, 70.6%) and non-menthol (11 of 17 subjects, 64.7%). Subjects reported smoking on a verage 18.5 cigarettes per day (range, 13 to 27 cigarettes per day), and the mean duration of smoking was 19.2 years (range, 5 to 36 years).

Medical histories are listed by subject in Appendix 16.2.3, [Listing 16.2.3.3](#). Fifteen subjects reported past medical history. The most common medical history finding was allergy. None of the medical history findings were considered to be clinically relevant.

Detailed listings of concomitant medications by subject are provided in Appendix 16.2.3, [Listing 16.2.3.4](#). No subject took an exclusionary medication. One subject took a concomitant medication during the study for treatment of an AE: Subject 14 took acetaminophen (1000 mg) for trauma secondary to a fall.

11.3 Measurements of Study Product Compliance

Study product consumption occurred under the direct supervision of study site staff. The start/stop times for use of each unit of study product consumed were recorded using electronic source and are presented by subject in Appendix 16.2.5, [Listing 16.2.5.3](#).

11.4 Biomarker, Questionnaire, and Expired Carbon Monoxide Results and Tabulations of Individual Subject Data

11.4.1 Biomarker Analyses

(b) (4)



(b) (4)



(b) (4)



(b) (4)



(b) (4)



11.4.2 Questionnaire Analyses

A summary of each MPSS scale item (depressed, anxious, irritable, restless, hungry, poor concentration, and current urge to smoke) is provided by product group and time point in Section 14.2.2, [Table 14.2.2.1](#). A corresponding summary of paired t-test results for the change in each item from pre-product administration (baseline) to each post-administration time point is provided in Section 14.2.2, [Table 14.2.2.2](#). A by-subject listing of MPSS scores by product and time point is provided in Appendix 16.2.6, [Listing 16.2.6.1](#). A summary of the results for each MPSS scale item is provided below.

(b) (4)



(b) (4)



(b) (4)



(b) (4)



(b) (4)



(b) (4)



(b) (4)



11.4.4 Statistical/Analytical Issues

The following subjects had missing assessments prior to 180 min after study product administration:

- Subject 03: 7.5 min and 10 min samples for UB cigarettes were not collected
- (b) (4)
- Subject 13: 10 min assessment for UB cigarette could not be determined due to insufficient sample volume
- (b) (4)

Nicotine uptake parameters were calculated for the subjects noted above without imputing the missing data, and for AUC_{0-180} and AUC_{adj} , the corresponding trapezoids were calculated using available surrounding data.

There were no missing assessments at 180 min, and therefore, no imputations for missing data were required.

11.4.5 Tabulation of Individual Response Data

Individual by-subject serum nicotine concentrations over time are provided in Section 14.2.1, [Figure 14.2.4.1](#) (unadjusted) and [Figure 14.2.4.2](#) (baseline adjusted).

11.4.6 By-Subject Displays

A by-subject listing of serum nicotine and cotinine concentrations at each time point and for each study product is presented in Appendix 16.2.5, [Listing 16.2.5.1](#).

By-subject listings of MPSS scores (by product and time point) and ECO levels are provided in Appendix 16.2.6, [Listing 16.2.6.1](#) and [Listing 16.2.6.3](#), respectively.

11.4.7 Biomarker, Questionnaire, and Expired Carbon Monoxide Conclusions

- As measured by AUC_{adj} and $T_{max(adj)}$, the extent of nicotine uptake was 2.3 to 4 times greater and the time to maximum nicotine concentration was 3.7 to 6 times shorter with UB cigarettes compared to the STPs.
- (b) (4)
- (b) (4)
- Use of UB cigarettes resulted in a 4 to 7.5 times greater maximum nicotine concentration (based on $C_{max(adj)}$) compared to STPs.
- (b) (4)

- (b) (4) [REDACTED]
- Use of UB cigarettes compared to STPs more often resulted in significant changes in tobacco abstinence symptoms, with significant reductions in feeling anxious, feeling irritable, feeling restless, having poor concentration, and current urge to smoke.
- The symptom of feeling depressed was not significantly impacted by the study products. No meaningful conclusion can be made for the symptom of feeling hungry since results were likely confounded because subjects were permitted to eat during test visits after product use.
- One subject had ECO levels requiring withdrawal from the study due to noncompliance with the protocol. All other subjects were confirmed to have ECO levels ≤ 12 ppm prior to undergoing procedures for each test visit.

12. SAFETY EVALUATION

12.1 Extent of Exposure

Study product consumption during test visits is summarized in Table 7. An individual by-subject listing of study product administration during test visits is provided in Appendix 16.2.5, [Listing 16.2.5.3](#).

Sixteen subjects received all study products; one subject (Subject 07) received only UB cigarette. The mean duration of study product use was approximately 7 min with UB cigarettes, approximately 21 min with Camel SNUS, and ranged from approximately 9 to 12 min with the STMs.

Table 7: Summary of Exposure to Study Products

Study Product Administration	Number of Subjects (%)	Product Use Duration (minutes, mean [SD])
UB Cigarette	17 (100.0%)	6.68 (1.440)
Camel SNUS	16 (94.4%) ^a	21.41 (5.064)

(b) (4)

Source: [Table 14.1.4](#) and [Listing 16.2.5.3](#)

SD=standard deviation

a. Subject 07 did not receive Camel SNUS, (b) (4) for blood collections; (b) (4)
(b) (4)

Start and stop times of study product sampling are listed by subject in Appendix 16.2.5, [Listing 16.2.5.4](#). After each sampling of study product, each subject reconfirmed consent to continue study participation.¹

At-home use of UB cigarettes prior to each test visit is presented by subject in Appendix 16.2.3, [Listing 16.2.3.5](#).

¹ During review of the final Listing 16.2.5.4, it was discovered for Subject 10 that reconfirmation of consent was listed as “No” at Test Visit 4, although the subject did provide consent to continue study participation (confirmed by study site staff). The data discrepancy was verified against the electronic source record, and the site confirmed the discrepancy resulted from a data entry error. It was agreed between CCD and the Sponsor that the data discrepancy did not impact the overall analysis and study conclusions and that unlocking of the database to correct the discrepancy was not required. The data discrepancy was documented as a Note to File.

12.2 Adverse Events

12.2.1 Brief Summary of Adverse Events

An overall summary of AEs by study product is provided in Table 8. The incidence of subjects with at least one AE, regardless of relationship to study product, was greater with concurrent use of STPs (6.3% to 25.0%) compared with UB cigarettes only (0%). Among STPs, Camel SNUS (b) (4) were temporally associated with the highest incidence of subjects with AEs (25.0% for each product), (b) (4) (b) (4). The PI considered four of the ten AEs to be potentially product related. All AEs were assessed as mild in severity by the PI.

No subject experienced an SAE (including death). No AEs resulted in cessation or interruption of study product usage. No AE resulted in subject discontinuation from the study.

Table 8: Overview of Adverse Events

Category	Number of Subjects (%)	
	UB Cigarette (N=17)	Camel SNUS (N=16)
At least one AE	0	4 (25.0%)
At least one AE leading to cessation/interruption of product usage	0	0
At least one AE leading to study discontinuation	0	0
At least one SAE	0	0

Source: Table 14.3.1, Listing 16.2.7.1, Listing 16.2.7.2, Listing 16.2.7.3

12.2.2 Display of Adverse Events

Adverse events are summarized by MedDRA SOC and preferred term in Section 14.3.1, Table 14.3.1. Adverse event severity and relationship to study product are provided in a by-subject listing in Appendix 16.2.7, Listing 16.2.7.1. Adverse events resulting in cessation or interruption of study product usage are listed Appendix 16.2.7, Listing 16.2.7.3.

12.2.3 Analysis of Adverse Events

A summary of AEs by SOC and preferred term is provided in Table 9.

Overall, the incidence of subjects with at least one AE was greater with STPs (6.3% to 25.0%) compared with UB cigarettes (0%). Among STPs, Camel SNUS and (b) (4) had the highest incidence of subjects with AEs (25.0% for each), (b) (4) (b) (4).

The most commonly reported AEs were throat irritation and headache, reported by two subjects each (one subject each in the Camel SNUS (b) (4) for both AEs).

Table 9: Summary of Adverse Events by System Organ Class and Preferred Term

System Organ Class Preferred Term	Number of Subjects (%)	
	UB Cigarette (N=17)	Camel SNUS (N=16)
Number of Subjects with at least one AE	0	4 (25.0%)
Blood and lymphatic system disorders	0	0
Anaemia	0	0
Gastrointestinal disorders	0	1 (6.3%)
Hiccups	0	0
Throat irritation	0	1 (6.3%)
Injury, poisoning and procedural complications	0	1 (6.3%)
Fall	0	1 (6.3%)
Nervous system disorders	0	1 (6.3%)
Dizziness	0	0
Headache	0	1 (6.3%)
Respiratory, thoracic and mediastinal disorders	0	1 (6.3%)
Nasal congestion	0	1 (6.3%)
Skin and subcutaneous tissue disorders	0	0
Skin laceration	0	0

Source: Table 14.3.1

Note: Subjects may have reported more than one event per SOC. Adverse events are temporally attributed to the last product received prior to reporting the event.

A summary of AEs considered potentially related to study product is provided in Table 10. Four subjects experienced AEs considered related to study product in the opinion of the PI. All study-product-related AEs occurred with STPs.

Table 10: Summary of Study-Product-Related Adverse Events

Preferred Term	Number of Subjects (%)		(b) (4)
	UB Cigarette (N=17)	Camel SNUS (N=16)	
Dizziness	0	0	
Hiccups	0	0	
Throat irritation	0	1 (6.3%)	

Source: [Table 14.3.1](#), [Listing 16.2.7.1](#)

The severity of each AE is listed by subject in Appendix 16.2.7, Listing 16.2.7.1. All AEs were mild in severity.

12.2.4 Listing of Adverse Events by Subject

A by-subject listing of all AEs is provided in Appendix 16.2.7, Listing 16.2.7.1. Listings of SAEs and AEs leading to cessation or interruption of study product usage are provided in Appendix 16.2.7, [Listing 16.2.7.2](#) and [Listing 16.2.7.3](#), respectively.

12.3 Deaths, Other Serious Adverse Events, and Other Significant Adverse Events

No deaths or other SAEs occurred during this study (Listing 16.2.7.2). No subject discontinued the study due to an AE (Listing 16.2.7.1). Narratives and analysis/discussion of deaths or other SAEs are not applicable.

12.3.1 Listing of Deaths, Other Serious Adverse Events and Other Significant Adverse Events

12.3.1.1 Deaths

No deaths occurred during this study (Listing 16.2.7.2).

12.3.1.2 Other Serious Adverse Events

No subject experienced a SAE during this study (Listing 16.2.7.2).

12.3.1.3 Other Significant Adverse Events

No subject discontinued the study due to an AE (Listing 16.2.7.1).

12.3.2 Narratives of Deaths, Other Serious Adverse Events and Certain Other Significant Adverse Events

Not applicable; there were no deaths, other SAEs, or other significant AEs during this study.

12.3.3 Analysis and Discussion of Deaths, Other Serious Adverse Events and Other Significant Adverse Events

Not applicable; there were no deaths, other SAEs, or other significant AEs during this study.

12.4 Clinical Laboratory Evaluation

12.4.1 Listing of Individual Laboratory Measurements by Subject and Each Abnormal Laboratory Value

Individual laboratory values by subject are provided in Appendix 16.2.8, [Listing 16.2.8.1](#) (CBC), [Listing 16.2.8.2](#) (CMP, triglycerides, and total cholesterol), and [Listing 16.2.8.3](#) (urinalysis).

12.4.2 Evaluation of Each Laboratory Parameter

Normal laboratory reference ranges are provided in [Appendix 16.1.10](#).

12.4.2.1 Laboratory Values over Time

Summaries of laboratory values are not provided.

12.4.2.2 Individual Subject Changes

Complete Blood Count

Hematology analytes with the greatest number of subjects experiencing shifts from normal baseline values were hemoglobin and red blood cells.

Five subjects had decreases in hemoglobin to or below the lower limit of normal; in all but one of these cases, the decreases were deemed NCS by the PI. The one case (Subject 03) of decreased hemoglobin assessed as CS is described in [Section 12.4.2.3](#) below.

Four subjects had decreases in red blood cells to below the lower limit of normal; in each case the decrease was deemed NCS by the PI.

Comprehensive Metabolic Profile

Few subjects had shifts in chemistry analytes from normal baseline values, and all were deemed NCS by the PI. Chemistry analytes with the greatest number of subjects experiencing shifts from normal baseline values were total protein (three subjects), calcium (two subjects), and total bilirubin (two subjects); all shifts involved decreases to below the lower limit of normal.

Triglycerides

One subject experienced a shift in triglyceride from a normal baseline value; the subject had an increase to above the upper limit of normal that was deemed NCS by the PI.

Total Cholesterol

No subject had a shift in total cholesterol from a normal baseline value.

Urinalysis

Two subjects had shifts in urinalysis values from normal baseline values: one subject had an increase in blood in urine from negative to 3+ and an increase in leukocytes from negative to

1+ and the other subject had an increase in blood in urine from negative to trace. Both subjects' changes were considered NCS by the PI.

12.4.2.3 Individual Clinically Significant Abnormalities

One subject (Subject 03) experienced a CS lab abnormality that was recorded as an AE. Subject 03, a 36-year-old Caucasian female, experienced a low hemoglobin value of 10.7 g/dL (normal range for females: 12.0–15.0 g/dL) at Test Visit 5, which was decreased from her baseline value of 13.3 g/dL measured at screening. The lab abnormality was recorded as anemia and was assessed by the PI as mild in severity and unrelated to study product. The subject also experienced decreases in red blood cells (4.67 MIL/uL at screening to 3.81 MIL/uL at final visit; normal range for females: 3.87–5.11 MIL/uL) and hematocrit (41.5% at screening to 33.7% at final visit; normal range for females: 36.0–46.0%), but neither was assessed as CS by the PI. The subject was notified of the low hemoglobin value via a telephone call 2 days after the test visit. During the call, the subject revealed a prior history of low hemoglobin and informed the PI that she would take an iron supplement and would follow-up with her primary physician. The PI considered the AE stabilized as no worsening was anticipated.

12.5 Vital Signs, Physical Findings, and Other Observations Related To Safety

12.5.1 Vital Signs

Observed values for systolic and diastolic blood pressures, oral temperature, heart rate, height, and weight at each time point where measured are listed for individual subjects in Appendix 16.2.8, [Listing 16.2.9](#).

There were minor fluctuations in blood pressure and heart rate measurements throughout the study, and four subjects had changes in weight of greater than 5 pounds (Subjects 04, 08, and 17 had increases ranging from 5.6 to 10.6 pounds; Subject 03 had a decrease of 8.8 pounds). No changes in vital sign measurements were considered clinically relevant or reported as AEs.

12.5.2 Physical Examinations Including Oral Examinations

Physical examination findings including oral examination are listed by subject in Appendix 16.2.6, [Listing 16.2.6.4](#). There were no CS changes in physical examinations, and no subjects had evidence of leukoplakia, other oral keratosis, or oral lesions at either screening or discharge visits.

12.5.3 Pregnancy Tests

No females who participated in this study tested positive for pregnancy at any visit (Appendix 16.2.2, [Listing 16.2.2](#)).

12.6 Safety Conclusions

The safety data support the following conclusions:

- A single unit each of UB cigarette, Camel SNUS, (b) (4) - (b) (4) following a 12-hour tobacco and nicotine abstinence period was well tolerated in generally healthy smokers.
- The overall incidence of subjects with AEs, regardless of relationship to study product, was greater with concurrent use of STPs (6.3% to 25.0%) compared with UB cigarettes alone (0%). Among STPs, Camel SNUS (b) (4) were temporally associated with the highest incidence of AEs (25.0% for each product), (b) (4) (b) (4).
- The most commonly reported AEs were throat irritation and headache, reported by two subjects each (one subject each in the Camel SNUS (b) (4) for both AEs).
- One subject experienced a CS decrease in hemoglobin, which was reported as anemia. The AE was assessed as mild in severity and unrelated to study product.
- No clinically relevant changes were noted in vital sign measurements, physical examinations, or oral examinations.

13. DISCUSSION AND OVERALL CONCLUSIONS

This was a single-center, randomized, open-label, crossover study to evaluate the serum nicotine uptake and tobacco abstinence symptoms with UB cigarettes, Camel SNUS, and (b) (4) in 17 current smokers in generally good health.

The extent of nicotine uptake (as measured by geometric LS mean for AUC_{0-180}) was significantly greater (approximately 2 to 3 times greater) with UB cigarettes compared to STPs ($p < 0.0001$ for all comparisons). Baseline-adjusted AUC values (adjusted for pre-existing nicotine prior to product administration) suggest that the difference across study products was somewhat more pronounced, with approximately 2.3 to 4 times greater nicotine AUC_{adj} with UB cigarettes compared with STPs ($p < 0.0001$ for all comparisons). (b) (4)

The extent of nicotine uptake from STPs relative to UB cigarettes (AUC_{ratio}) ranged from 24.4% to 42.6%. (b) (4)

Geometric LS mean for nicotine $C_{max(adj)}$ was significantly greater (approximately 4 to 7.5 times greater) with UB cigarettes compared with STPs ($p < 0.0001$ for all comparisons). (b) (4)

LS mean nicotine $T_{max(adj)}$ was significantly lower (approximately 3.7 to 6 times lower) with UB cigarette compared with STPs ($p < 0.0001$ for all comparisons). (b) (4)

Use of UB cigarettes compared to STPs more often resulted in significant changes in tobacco abstinence symptoms, with significant reductions in feeling anxious, feeling irritable, feeling restless, having poor concentration, and current urge to smoke. These findings are consistent with previous studies that demonstrated significantly less suppression of tobacco abstinence symptoms with Ariva compared to cigarettes (Blank *et al.*, 2008; Cobb *et al.*, 2009; Kotlyar *et al.*, 2007). The symptom of feeling depressed was not significantly impacted by the study products. Results for feeling hungry were likely confounded because subjects were permitted to eat during test visits after product use, and no meaningful conclusions can be made.

Statistically significant reductions from baseline in feeling anxious ($p < 0.05$) were observed at most post-administration time points with UB cigarettes (b) (4). The use of UB cigarettes significantly reduced the feeling of being anxious through 150 min after administration. (b) (4)

Statistically significant changes from baseline in feeling irritable ($p < 0.05$) were observed with UB cigarettes only, with reductions at 15, 30, 45, 60, 90, 150, and 180 min. Small reductions in feeling irritable were noted with STPs, but none were statistically significant. It is noted that the significant reductions with UB cigarettes might be attributed to a higher baseline rating with UB cigarettes compared with the other study products.

Slight fluctuations from baseline in feeling restless occurred for all products, but only a decrease with UB cigarettes at 15 min after administration was statistically significant ($p < 0.05$). For all products, nominal decreases were observed during the first 30 to 60 min, followed by increases by 150 min.

Reductions from baseline in poor concentration were statistically significant ($p < 0.05$) at every post-administration time point with UB cigarettes, and (b) (4). Use of Camel SNUS, (b) (4) did not produce significant changes in poor concentration.

Through 120 min after administration, current urge to smoke was significantly reduced from baseline ($p < 0.05$) with each study product, with the greatest decreases occurring with UB cigarettes. At 150 minutes, significant reductions continued with UB cigarettes (b) (4), but not with Camel SNUS. At 180 min, significant reductions were observed only with UB cigarettes (b) (4).

No deaths, SAEs, or subject discontinuations due to AEs were reported during this study, and no AE resulted in cessation or interruption of study product. No unexpected or unusual side effects were observed with the use of study products. All AEs were mild in severity.

The incidence of subjects with at least one AE, regardless of relationship to study product, was greater with concurrent use of STPs (6.3% to 25.0%) compared with UB cigarettes only (0%). Among STPs, Camel SNUS (b) (4) were temporally associated with the highest incidence of subjects with AEs (25.0% for each product), (b) (4) 3 (b) (4). The most commonly reported AEs were throat irritation and headache, reported by two subjects each (one subject each in the Camel SNUS (b) (4) (b) (4) for both AEs).

Safety laboratory parameters with the greatest number of subjects experiencing shifts from normal baseline values were hemoglobin and red blood cells. Five subjects had decreases in hemoglobin to or below the lower limit of normal and four subjects had decreases in red

blood cells to below the lower limit of normal. One shift in hemoglobin (13.3 g/dL to 10.7 g/dL [female normal range: 12.0-15.0 g/dL]), in a 36-year-old female, was assessed as CS by the PI. The lab abnormality was recorded as anemia and was assessed as mild in severity and unrelated to study product. No other shifts in safety laboratory parameters were considered CS.

Minor fluctuations in blood pressure and heart rate measurements throughout the study were observed. Four subjects had increases or decreases in weight of greater than 5 pounds (range of 5.6 to 10.6 pounds). No changes in vital sign measurement were considered clinically relevant or reported as AEs. Physical and oral examinations showed no clinically relevant changes or abnormalities following use of study products.

**14. TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN
THE TEXT**

14.1 Demographic Data

Table Number	Table Title
14.1.1	Subject Disposition
14.1.2	Demographics and Characteristics at Screening
14.1.3	Usual Brand Summary
14.1.4	In-Clinic Product Use Duration (minutes) – Summary by Product Group

Table 14.1.1
Subject Disposition

	All Randomized Subjects (N=17)
Completed the Study	16 (94.1%)
Discontinued from the Study	1 (5.9%)
Reason for Discontinuation	
Adverse Event, specify	0
Protocol Noncompliance, specify	1 (5.9%)
Consent Withdrawn	0
Pregnancy	0
Inability to communicate and/or unwillingness to cooperate with the investigator, specify	0
Lost to follow-up	0
Change in status with the respect to an I/E criterion that is clinically relevant and/or could affect subject safety, specify	0
Other, specify	0

Data Source: [Listing 16.2.1](#)

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/TABLE/T14010100.SAS EXECUTED: 19AUG2012 15:42

Table 14.1.2
Demographics and Characteristics at Screening

	All Randomized Subjects (N=17)
Sex	
Female	11 (64.7%)
Male	6 (35.3%)
Age (years)	
n	17
Mean (SD)	36.1 (9.36)
Median	35.0
Min, Max	25, 53
Race	
African American	1 (5.9%)
American Indian	0
Asian	0
Caucasian	16 (94.1%)
Hispanic/Latino	0
Native Hawaiian	0
Height (in)	
n	17
Mean (SD)	66.50 (4.370)
Median	65.00
Min, Max	61.0, 74.0

Data Source: [Listing 16.2.3.1](#), [16.2.6.1](#), and [16.2.6.2](#)

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/TABLE/T14010200.SAS EXECUTED: 09OCT2012 16:29

Table 14.1.2
Demographics and Characteristics at Screening

	All Randomized Subjects (N=17)
Weight (lb)	
n	17
Mean (SD)	181.72 (48.272)
Median	170.00
Min, Max	123.2, 267.0
Mood and Physical Symptoms Scale Item 1: Depressed	
n	17
Mean (SD)	1.1 (0.24)
Median	1.0
Min, Max	1, 2
Mood and Physical Symptoms Scale Item 2: Anxious	
n	17
Mean (SD)	1.4 (0.61)
Median	1.0
Min, Max	1, 3
Mood and Physical Symptoms Scale Item 3: Irritable	
n	17
Mean (SD)	1.2 (0.53)
Median	1.0
Min, Max	1, 3

Data Source: [Listing 16.2.3.1](#), [16.2.6.1](#), and [16.2.6.2](#)

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/TABLE/T14010200.SAS EXECUTED: 09OCT2012 16:29

Table 14.1.2
Demographics and Characteristics at Screening

	All Randomized Subjects (N=17)
Mood and Physical Symptoms Scale Item 4: Restless	
n	17
Mean (SD)	1.3 (0.59)
Median	1.0
Min, Max	1, 3
Mood and Physical Symptoms Scale Item 5: Hungry	
n	17
Mean (SD)	2.2 (0.66)
Median	2.0
Min, Max	1, 3
Mood and Physical Symptoms Scale Item 6: Poor Concentration	
n	17
Mean (SD)	1.2 (0.66)
Median	1.0
Min, Max	1, 3
Mood and Physical Symptoms Scale Item 7: How strong is your current urge to smoke?	
n	17
Mean (SD)	1.5 (0.94)
Median	1.0
Min, Max	0, 3

Data Source: [Listing 16.2.3.1](#), [16.2.6.1](#), and [16.2.6.2](#)

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/TABLE/T14010200.SAS EXECUTED: 09OCT2012 16:29

Table 14.1.2
Demographics and Characteristics at Screening

	All Randomized Subjects (N=17)
Fagerström Q1: How soon after you wake up do you smoke your first cigarette?	
Within 5 Minutes	5 (29.4%)
6-30 Minutes	8 (47.1%)
31-60 Minutes	3 (17.6%)
After 60 Minutes	1 (5.9%)
Fagerström Q2: Do you find it difficult to refrain from smoking in places where it is forbidden, e.g. in church, at the library, in cinema, etc.?	
Yes	7 (41.2%)
No	10 (58.8%)
Fagerström Q3: Which cigarette would you hate most to give up?	
The first one in the morning	8 (47.1%)
Any other	9 (52.9%)
Fagerström Q4: How many cigarettes per day do you smoke?	
<=10	0
11-20	13 (76.5%)
21-30	4 (23.5%)
>=31	0

Data Source: [Listing 16.2.3.1](#), [16.2.6.1](#), and [16.2.6.2](#)

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/TABLE/T14010200.SAS EXECUTED: 09OCT2012 16:29

Table 14.1.2
Demographics and Characteristics at Screening

	All Randomized Subjects (N=17)
Fagerström Q5: Do you smoke more frequently during the first hours after waking than during the rest of the day?	
Yes	7 (41.2%)
No	10 (58.8%)
Fagerström Q6: Do you smoke if you are so ill that you are in bed most of the day?	
Yes	8 (47.1%)
No	9 (52.9%)
Fagerström Total Score	
n	17
Mean (SD)	5.0 (2.06)
Median	5.0
Min, Max	1, 8

Data Source: [Listing 16.2.3.1](#), [16.2.6.1](#), and [16.2.6.2](#)

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/TABLE/T14010200.SAS EXECUTED: 09OCT2012 16:29

Table 14.1.3
Usual Brand Summary

	All Randomized Subjects (N=17)
Usual Brand Name	
Camel Blue	1 (5.9%)
Camel Filters	1 (5.9%)
Camel Menthol Silver	3 (17.6%)
Marlboro Gold	2 (11.8%)
Marlboro Gold Special Blend	1 (5.9%)
Marlboro Menthol Gold	1 (5.9%)
Marlboro Red	1 (5.9%)
Marlboro Special Blend Red	1 (5.9%)
Marlboro Special Blends Gold	1 (5.9%)
Natural American Spirit	1 (5.9%)
Newport Non-Menthol Red	1 (5.9%)
Pall Mall Red	1 (5.9%)
Salem Gold	1 (5.9%)
Winston Gold	1 (5.9%)
Length	
72 MM	0
83 MM	12 (70.6%)
85 MM	0
99 MM	0
100 MM	5 (29.4%)
120 MM	0
Packaging	
Soft pack	0
Hard pack	17 (100.0%)
Type	
Menthol	6 (35.3%)
Non-menthol	11 (64.7%)

Data Source: [Listing 16.2.3.2](#)

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/TABLE/T14010300.SAS EXECUTED: 19AUG2012 15:42

Table 14.1.3
Usual Brand Summary

	All Randomized Subjects (N=17)
Filter Type	
Standard	17 (100.0%)
Non-filter	0
Number of cigarettes the subject typically smokes per day	
n	17
Mean (SD)	18.5 (3.48)
Median	20.0
Min, Max	13, 27
Length of time subject has smoked (years)	
n	17
Mean (SD)	19.2 (7.67)
Median	19.0
Min, Max	5, 36

Data Source: [Listing 16.2.3.2](#)

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/TABLE/T14010300.SAS EXECUTED: 19AUG2012 15:42

Table 14.1.4
In-clinic Product Use Duration (minutes) - Summary by Product Group

(b) (4)



14.2 Biomarker and Questionnaire Data

14.2.1 Biomarker Data

Table Number	Table Title
14.2.1.1	Serum Concentrations - Summary by Product and Time Point for Cotinine (pre-product only) and Nicotine
14.2.1.2	Summary of Derived Nicotine Uptake Parameters and Cotinine at Time 0 by Product Group
14.2.1.3	Summary of Pairwise Comparisons for Derived Nicotine Uptake Parameters and Cotinine at Time 0

Figure Number	Figure Title
14.2.1	Boxplot Summary of Serum Nicotine Uptake Parameters, All Randomized Subjects
14.2.2	Boxplot Summary of Serum Cotinine at Time 0, All Randomized Subjects
14.2.3.1	Mean Serum Nicotine Concentration vs. Time, All Randomized Subjects
14.2.3.2	Mean Serum Nicotine Concentration (Baseline Adjusted) vs. Time, All Randomized Subjects
14.2.4.1	Individual Serum Nicotine Concentration vs. Time, All Randomized Subjects
14.2.4.2	Individual Serum Nicotine Concentration (Baseline Adjusted) vs. Time, All Randomized Subjects

Table 14.2.1.1

Serum Concentrations - Summary by Product and Time Point for Cotinine (pre-product only) and Nicotine

(b) (4)



Table 14.2.1.1

Serum Concentrations - Summary by Product and Time Point for Cotinine (pre-product only) and Nicotine

(b) (4)



Table 14.2.1.1
Serum Concentrations - Summary by Product and Time Point for Cotinine (pre-product only) and Nicotine

(b) (4)



Table 14.2.1.1

Serum Concentrations - Summary by Product and Time Point for Cotinine (pre-product only) and Nicotine

(b) (4)



Table 14.2.1.1
Serum Concentrations - Summary by Product and Time Point for Cotinine (pre-product only) and Nicotine

(b) (4)



Table 14.2.1.1

Serum Concentrations - Summary by Product and Time Point for Cotinine (pre-product only) and Nicotine

(b) (4)



Table 14.2.1.1

Serum Concentrations - Summary by Product and Time Point for Cotinine (pre-product only) and Nicotine

(b) (4)



Table 14.2.1.2

Serum Concentrations - Summary of Derived Nicotine Uptake Parameters and Cotinine at Time 0 by Product Group

(b) (4)



Table 14.2.1.2

Serum Concentrations - Summary of Derived Nicotine Uptake Parameters and Cotinine at Time 0 by Product Group

(b) (4)



Table 14.2.1.3

Summary of Pairwise Comparisons for Derived Nicotine Uptake Parameters and Cotinine at Time 0

(b) (4)



Figure 14.2.1
Boxplot Summary of Serum Nicotine Uptake Parameters
All Randomized Subjects

(b) (4)



Figure 14.2.1
Boxplot Summary of Serum Nicotine Uptake Parameters
All Randomized Subjects

(b) (4)



Figure 14.2.1
Boxplot Summary of Serum Nicotine Uptake Parameters
All Randomized Subjects

(b) (4)



Figure 14.2.1
Boxplot Summary of Serum Nicotine Uptake Parameters
All Randomized Subjects

(b) (4)



Figure 14.2.1
Boxplot Summary of Serum Nicotine Uptake Parameters
All Randomized Subjects

(b) (4)



Figure 14.2.1
Boxplot Summary of Serum Nicotine Uptake Parameters
All Randomized Subjects

(b) (4)



Figure 14.2.2
Boxplot Summary of Serum Cotinine at Time 0
All Randomized Subjects

(b) (4)



Figure 14.2.3.1
Mean Serum Nicotine Concentration vs Time
All Randomized Subjects

(b) (4)



Figure 14.2.3.2
Mean Serum Nicotine Concentration (Baseline Adjusted) vs Time
All Randomized Subjects

(b) (4)



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Figure 14.2.4.1
Individual Serum Nicotine Concentration vs Time
All Randomized Subjects

Subject: 01

(b) (4)



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Figure 14.2.4.1
Individual Serum Nicotine Concentration vs Time
All Randomized Subjects

Subject: 02

(b) (4)



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Figure 14.2.4.1
Individual Serum Nicotine Concentration vs Time
All Randomized Subjects

Subject: 03

(b) (4)



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Figure 14.2.4.1
Individual Serum Nicotine Concentration vs Time
All Randomized Subjects

Subject: 04

(b) (4)



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Figure 14.2.4.1
Individual Serum Nicotine Concentration vs Time
All Randomized Subjects

Subject: 05

(b) (4)



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Figure 14.2.4.1
Individual Serum Nicotine Concentration vs Time
All Randomized Subjects

Subject: 06

(b) (4)

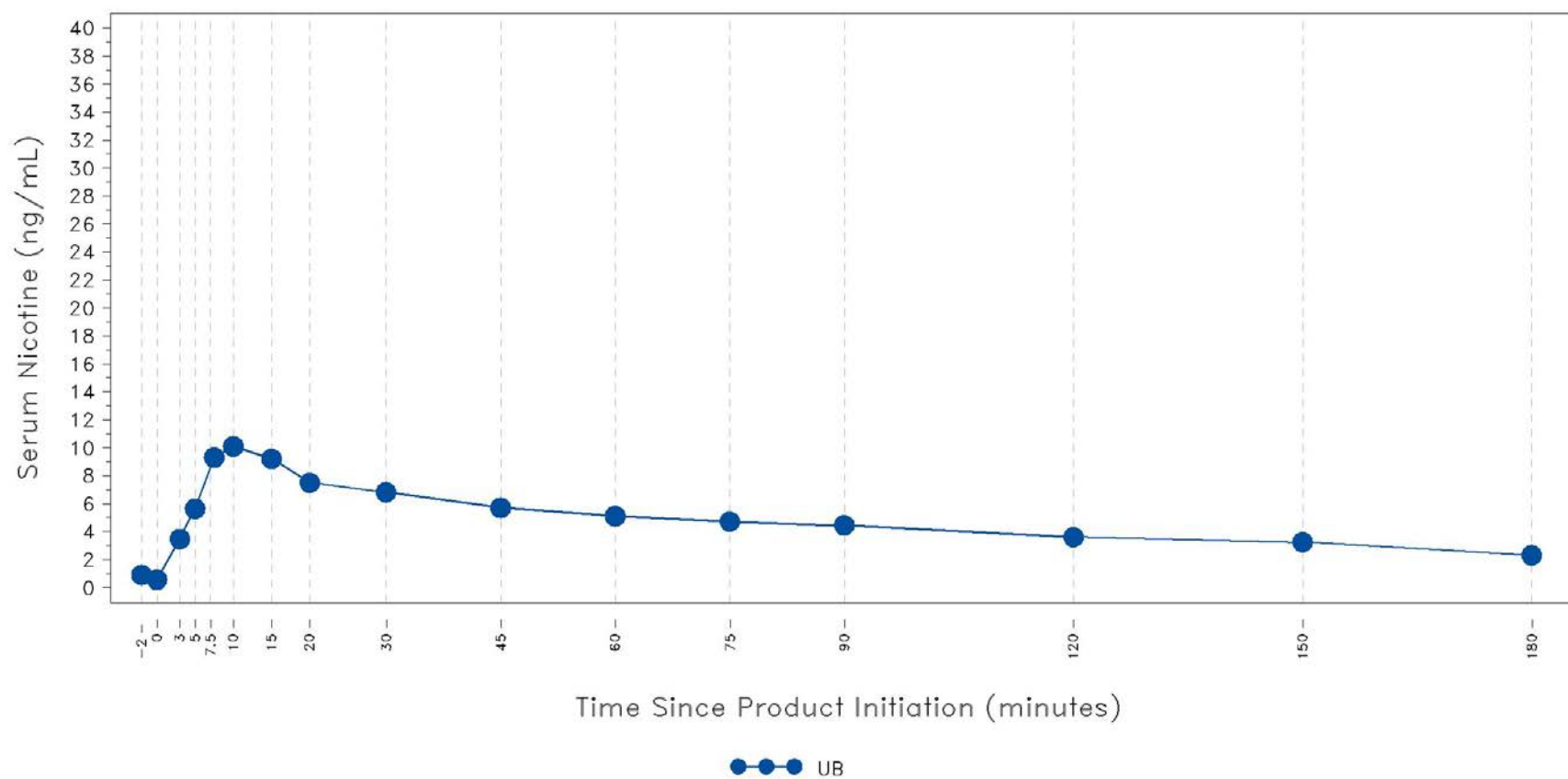


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Figure 14.2.4.1
Individual Serum Nicotine Concentration vs Time
All Randomized Subjects

Subject: 07



Data Source: Table 14.2.1.1

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Figure 14.2.4.1
Individual Serum Nicotine Concentration vs Time
All Randomized Subjects

Subject: 08

(b) (4)



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Figure 14.2.4.1
Individual Serum Nicotine Concentration vs Time
All Randomized Subjects

Subject: 09

(b) (4)



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Figure 14.2.4.1
Individual Serum Nicotine Concentration vs Time
All Randomized Subjects

Subject: 10

(b) (4)



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Figure 14.2.4.1
Individual Serum Nicotine Concentration vs Time
All Randomized Subjects

Subject: 11

(b) (4)



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Figure 14.2.4.1
Individual Serum Nicotine Concentration vs Time
All Randomized Subjects

Subject: 12

(b) (4)



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Figure 14.2.4.1
Individual Serum Nicotine Concentration vs Time
All Randomized Subjects

Subject: 13

(b) (4)



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Figure 14.2.4.1
Individual Serum Nicotine Concentration vs Time
All Randomized Subjects

Subject: 14

(b) (4)



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Figure 14.2.4.1
Individual Serum Nicotine Concentration vs Time
All Randomized Subjects

Subject: 15

(b) (4)



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Figure 14.2.4.1
Individual Serum Nicotine Concentration vs Time
All Randomized Subjects

Subject: 16

(b) (4)



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Figure 14.2.4.1
Individual Serum Nicotine Concentration vs Time
All Randomized Subjects

Subject: 17

(b) (4)



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Figure 14.2.4.2
Individual Serum Nicotine Concentration (Baseline Adjusted) vs Time
All Randomized Subjects

Subject: 01

(b) (4)



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Protocol Number: CSD1101

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Figure 14.2.4.2
Individual Serum Nicotine Concentration (Baseline Adjusted) vs Time
All Randomized Subjects

Subject: 02

(b) (4)



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Figure 14.2.4.2
Individual Serum Nicotine Concentration (Baseline Adjusted) vs Time
All Randomized Subjects

Subject: 03

(b) (4)



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Protocol Number: CSD1101

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Figure 14.2.4.2
Individual Serum Nicotine Concentration (Baseline Adjusted) vs Time
All Randomized Subjects

Subject: 04

(b) (4)



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Protocol Number: CSD1101

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Figure 14.2.4.2
Individual Serum Nicotine Concentration (Baseline Adjusted) vs Time
All Randomized Subjects

Subject: 05

(b) (4)



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Protocol Number: CSD1101

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Figure 14.2.4.2
Individual Serum Nicotine Concentration (Baseline Adjusted) vs Time
All Randomized Subjects

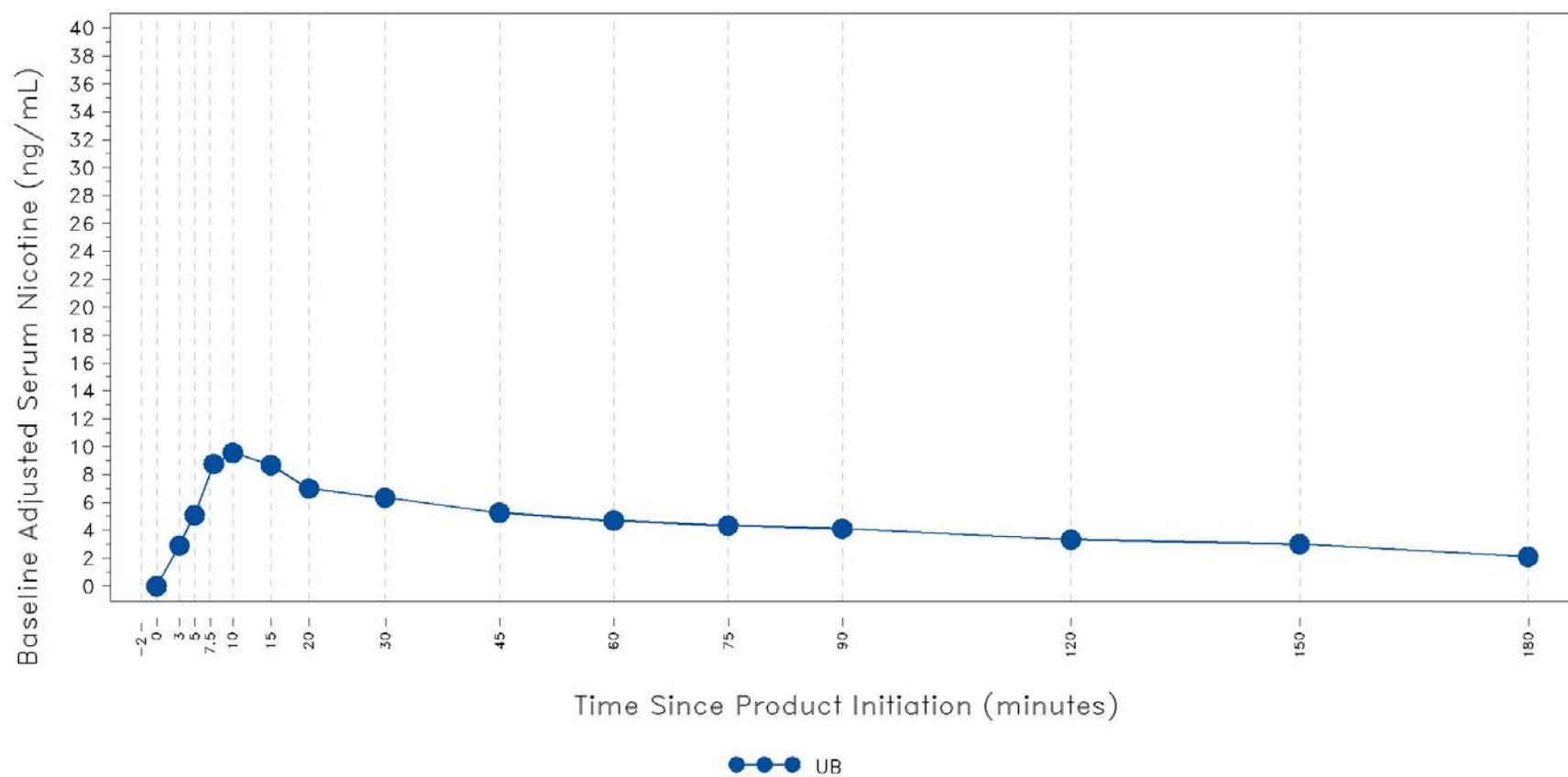
Subject: 06

(b) (4)



Figure 14.2.4.2
Individual Serum Nicotine Concentration (Baseline Adjusted) vs Time
All Randomized Subjects

Subject: 07



Data Source: Table 14.2.1.1

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Figure 14.2.4.2
Individual Serum Nicotine Concentration (Baseline Adjusted) vs Time
All Randomized Subjects

Subject: 08

(b) (4)



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Figure 14.2.4.2
Individual Serum Nicotine Concentration (Baseline Adjusted) vs Time
All Randomized Subjects

Subject: 09

(b) (4)



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Figure 14.2.4.2
Individual Serum Nicotine Concentration (Baseline Adjusted) vs Time
All Randomized Subjects

Subject: 10

(b) (4)



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Figure 14.2.4.2
Individual Serum Nicotine Concentration (Baseline Adjusted) vs Time
All Randomized Subjects

Subject: 11

(b) (4)



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Figure 14.2.4.2
Individual Serum Nicotine Concentration (Baseline Adjusted) vs Time
All Randomized Subjects

Subject: 12

(b) (4)



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Figure 14.2.4.2
Individual Serum Nicotine Concentration (Baseline Adjusted) vs Time
All Randomized Subjects

Subject: 13

(b) (4)



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Figure 14.2.4.2
Individual Serum Nicotine Concentration (Baseline Adjusted) vs Time
All Randomized Subjects

Subject: 14

(b) (4)



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Figure 14.2.4.2
Individual Serum Nicotine Concentration (Baseline Adjusted) vs Time
All Randomized Subjects

Subject: 15

(b) (4)



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Figure 14.2.4.2
Individual Serum Nicotine Concentration (Baseline Adjusted) vs Time
All Randomized Subjects

Subject: 16

(b) (4)



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Figure 14.2.4.2
Individual Serum Nicotine Concentration (Baseline Adjusted) vs Time
All Randomized Subjects

Subject: 17

(b) (4)



14.2.2 Questionnaire Data

Table Number	Table Title
14.2.2.1	Mood and Physical Symptoms Scale - Summary by Product Group Over Time
14.2.2.2	Mood and Physical Symptoms Scale - Summary of Paired t-tests

Figure Number	Figure Title
14.3.1	Individual Mood and Physical Symptoms Scale Items vs. Time, All Randomized Subjects

Table 14.2.2.1
Mood and Physical Symptoms Scale - Summary by Product Group Over Time

Scale Item	Minutes Post Admin.		[UB] Subject - specific UB Cigarette	[1] Camel SNUS	(b) (4)
Depressed	Pre 0	n	17	16	
		Mean (SD)	1.1 (0.24)	1.1 (0.25)	
		Median	1.0	1.0	
		Min, Max	1, 2	1, 2	
	5'	n	17	16	
		Mean (SD)	1.0 (0.00)	1.1 (0.25)	
		Median	1.0	1.0	
		Min, Max	1, 1	1, 2	
	15'	n	17	16	
		Mean (SD)	1.0 (0.00)	1.1 (0.25)	
		Median	1.0	1.0	
		Min, Max	1, 1	1, 2	
	30'	n	17	16	
		Mean (SD)	1.1 (0.24)	1.1 (0.34)	
		Median	1.0	1.0	
		Min, Max	1, 2	1, 2	
	45'	n	17	16	
		Mean (SD)	1.1 (0.24)	1.2 (0.54)	
		Median	1.0	1.0	
		Min, Max	1, 2	1, 3	
	60'	n	17	16	
		Mean (SD)	1.1 (0.33)	1.1 (0.34)	
		Median	1.0	1.0	
		Min, Max	1, 2	1, 2	

Data Source: [Listing 16.2.6.1](#)

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Table 14.2.2.1
Mood and Physical Symptoms Scale - Summary by Product Group Over Time

Scale Item	Minutes Post Admin.	[UB] Subject - specific			[1] Camel SNUS	(b) (4)
		UB Cigarette				
Depressed	90'	n	17		16	
		Mean (SD)	1.1 (0.33)		1.1 (0.34)	
		Median	1.0		1.0	
		Min, Max	1, 2		1, 2	
	120'	n	17		16	
		Mean (SD)	1.1 (0.24)		1.1 (0.34)	
		Median	1.0		1.0	
		Min, Max	1, 2		1, 2	
	150'	n	17		16	
		Mean (SD)	1.0 (0.00)		1.1 (0.34)	
		Median	1.0		1.0	
		Min, Max	1, 1		1, 2	
	180'	n	17		16	
		Mean (SD)	1.0 (0.00)		1.1 (0.34)	
		Median	1.0		1.0	
		Min, Max	1, 1		1, 2	
Data Source: Listing 16.2.6.1						

Data Source: [Listing 16.2.6.1](#)

Table 14.2.2.1
Mood and Physical Symptoms Scale - Summary by Product Group Over Time

Scale Item	Minutes Post Admin.	[UB] Subject - specific UB Cigarette			[1] Camel SNUS	(b) (4)
		n	Mean (SD)	Median		
Anxious	Pre 0	17	1.8 (0.73)	2.0	16	
		1.8 (0.73)	2.0	1.0	1.4 (0.63)	
		1, 3	1, 3	1, 3	1, 3	
		1, 3	1, 3	1, 3	1, 3	
	5'	17	1.2 (0.56)	1.0	16	
		1.2 (0.56)	1.0	1.0	1.3 (0.48)	
		1, 3	1, 3	1, 2	1, 2	
		1, 3	1, 3	1, 2	1, 2	
	15'	17	1.4 (0.51)	1.0	16	
		1.4 (0.51)	1.0	1.0	1.2 (0.40)	
		1, 2	1, 2	1, 2	1, 2	
		1, 2	1, 2	1, 2	1, 2	
	30'	17	1.3 (0.59)	1.0	16	
		1.3 (0.59)	1.0	1.0	1.2 (0.40)	
		1, 3	1, 3	1, 2	1, 2	
		1, 3	1, 3	1, 2	1, 2	
	45'	17	1.3 (0.59)	1.0	16	
		1.3 (0.59)	1.0	1.0	1.3 (0.58)	
		1, 3	1, 3	1, 3	1, 3	
		1, 3	1, 3	1, 3	1, 3	
	60'	17	1.2 (0.39)	1.0	16	
		1.2 (0.39)	1.0	1.0	1.3 (0.58)	
		1, 2	1, 2	1, 3	1, 3	
		1, 2	1, 2	1, 3	1, 3	

Data Source: [Listing 16.2.6.1](#)

Table 14.2.2.1
Mood and Physical Symptoms Scale - Summary by Product Group Over Time

Scale Item	Minutes Post Admin.	[UB] Subject - specific			[1] Camel SNUS	(b) (4)
			UB Cigarette			
Anxious	90'	n	17		16	
		Mean (SD)	1.2 (0.56)		1.2 (0.54)	
		Median	1.0		1.0	
		Min, Max	1, 3		1, 3	
	120'	n	17		16	
		Mean (SD)	1.4 (0.71)		1.3 (0.60)	
		Median	1.0		1.0	
		Min, Max	1, 3		1, 3	
	150'	n	17		16	
		Mean (SD)	1.4 (0.61)		1.3 (0.79)	
		Median	1.0		1.0	
		Min, Max	1, 3		1, 4	
	180'	n	17		16	
		Mean (SD)	1.6 (0.93)		1.3 (0.79)	
		Median	1.0		1.0	
		Min, Max	1, 4		1, 4	

Data Source: [Listing 16.2.6.1](#)

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Table 14.2.2.1
Mood and Physical Symptoms Scale - Summary by Product Group Over Time

Scale Item	Minutes Post Admin.	[UB] Subject - specific			[1] Camel SNUS
			UB Cigarette		
Irritable	Pre 0	n	17	16	(b) (4)
		Mean (SD)	1.8 (0.90)	1.4 (0.63)	
		Median	2.0	1.0	
		Min, Max	1, 4	1, 3	
	5'	n	17	16	
		Mean (SD)	1.2 (0.75)	1.3 (0.45)	
		Median	1.0	1.0	
		Min, Max	1, 4	1, 2	
	15'	n	17	16	
		Mean (SD)	1.1 (0.24)	1.2 (0.40)	
		Median	1.0	1.0	
		Min, Max	1, 2	1, 2	
	30'	n	17	16	
		Mean (SD)	1.1 (0.33)	1.2 (0.40)	
		Median	1.0	1.0	
		Min, Max	1, 2	1, 2	
	45'	n	17	16	
		Mean (SD)	1.2 (0.56)	1.3 (0.58)	
		Median	1.0	1.0	
		Min, Max	1, 3	1, 3	
	60'	n	17	16	
		Mean (SD)	1.2 (0.39)	1.3 (0.60)	
		Median	1.0	1.0	
		Min, Max	1, 2	1, 3	

Data Source: [Listing 16.2.6.1](#)

Table 14.2.2.1
Mood and Physical Symptoms Scale - Summary by Product Group Over Time

Scale Item	Minutes Post Admin.		[UB] Subject - specific UB Cigarette	[1] Camel SNUS
Irritable	90'	n	17	16
		Mean (SD)	1.2 (0.53)	1.3 (0.60)
		Median	1.0	1.0
		Min, Max	1, 3	1, 3
	120'	n	17	16
		Mean (SD)	1.4 (0.79)	1.3 (0.60)
		Median	1.0	1.0
		Min, Max	1, 4	1, 3
	150'	n	17	16
		Mean (SD)	1.4 (0.61)	1.3 (0.60)
		Median	1.0	1.0
		Min, Max	1, 3	1, 3
	180'	n	17	16
		Mean (SD)	1.4 (0.70)	1.4 (0.62)
		Median	1.0	1.0
		Min, Max	1, 3	1, 3

(b) (4)

Data Source: [Listing 16.2.6.1](#)

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Table 14.2.2.1
Mood and Physical Symptoms Scale - Summary by Product Group Over Time

Scale Item	Minutes Post Admin.		[UB] Subject - specific UB Cigarette	[1] Camel SNUS	(b) (4)
Restless	Pre 0	n	17	16	
		Mean (SD)	1.6 (0.70)	1.3 (0.70)	
		Median	2.0	1.0	
		Min, Max	1, 3	1, 3	
	5'	n	17	16	
		Mean (SD)	1.4 (0.61)	1.1 (0.34)	
		Median	1.0	1.0	
		Min, Max	1, 3	1, 2	
	15'	n	17	16	
		Mean (SD)	1.2 (0.39)	1.1 (0.34)	
		Median	1.0	1.0	
		Min, Max	1, 2	1, 2	
	30'	n	17	16	
		Mean (SD)	1.4 (0.49)	1.1 (0.34)	
		Median	1.0	1.0	
		Min, Max	1, 2	1, 2	
	45'	n	17	16	
		Mean (SD)	1.3 (0.47)	1.3 (0.48)	
		Median	1.0	1.0	
		Min, Max	1, 2	1, 2	
	60'	n	17	16	
		Mean (SD)	1.4 (0.61)	1.4 (0.62)	
		Median	1.0	1.0	
		Min, Max	1, 3	1, 3	
Data Source: Listing 16.2.6.1					

Data Source: [Listing 16.2.6.1](#)

Table 14.2.2.1
Mood and Physical Symptoms Scale - Summary by Product Group Over Time

Scale Item	Minutes Post Admin.		[UB] Subject - specific UB Cigarette	[1] Camel SNUS
Restless	90'	n	17	16
		Mean (SD)	1.5 (0.62)	1.5 (0.63)
		Median	1.0	1.0
		Min, Max	1, 3	1, 3
	120'	n	17	16
		Mean (SD)	1.7 (0.85)	1.5 (0.82)
		Median	2.0	1.0
		Min, Max	1, 4	1, 4
	150'	n	17	16
		Mean (SD)	1.8 (0.95)	1.6 (0.81)
		Median	2.0	1.5
		Min, Max	1, 4	1, 4
	180'	n	17	16
		Mean (SD)	1.9 (0.93)	1.7 (0.87)
		Median	2.0	1.5
		Min, Max	1, 4	1, 4

(b) (4)

Data Source: [Listing 16.2.6.1](#)

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Table 14.2.2.1
Mood and Physical Symptoms Scale - Summary by Product Group Over Time

Scale Item	Minutes Post Admin.	[UB] Subject - specific			(b) (4)
			UB Cigarette	[1] Camel SNUS	
Hungry	Pre 0	n	17	16	
		Mean (SD)	2.0 (1.06)	1.3 (0.45)	
		Median	2.0	1.0	
		Min, Max	1, 5	1, 2	
	5'	n	17	16	
		Mean (SD)	1.8 (0.97)	1.2 (0.40)	
		Median	2.0	1.0	
		Min, Max	1, 4	1, 2	
	15'	n	17	16	
		Mean (SD)	1.8 (0.83)	1.3 (0.45)	
		Median	2.0	1.0	
		Min, Max	1, 4	1, 2	
	30'	n	17	16	
		Mean (SD)	1.6 (0.62)	1.4 (0.62)	
		Median	2.0	1.0	
		Min, Max	1, 3	1, 3	
	45'	n	17	16	
		Mean (SD)	1.7 (0.77)	1.5 (0.63)	
		Median	2.0	1.0	
		Min, Max	1, 3	1, 3	
	60'	n	17	16	
		Mean (SD)	1.9 (0.75)	1.3 (0.48)	
		Median	2.0	1.0	
		Min, Max	1, 3	1, 2	

Data Source: [Listing 16.2.6.1](#)

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/TABLE/T14020201.SAS EXECUTED: 19AUG2012 15:43

Table 14.2.2.1
Mood and Physical Symptoms Scale - Summary by Product Group Over Time

Scale Item	Minutes Post Admin.		[UB] Subject - specific UB Cigarette	[1] Camel SNUS
Hungry	90'	n	17	16
		Mean (SD)	1.8 (0.75)	1.3 (0.70)
		Median	2.0	1.0
		Min, Max	1, 3	1, 3
	120'	n	17	16
		Mean (SD)	1.8 (1.01)	1.6 (0.81)
		Median	1.0	1.0
		Min, Max	1, 4	1, 3
	150'	n	17	16
		Mean (SD)	2.1 (1.05)	1.6 (1.09)
		Median	2.0	1.0
		Min, Max	1, 4	1, 4
	180'	n	17	16
		Mean (SD)	2.3 (1.21)	1.8 (1.18)
		Median	2.0	1.0
		Min, Max	1, 4	1, 4

(b) (4)

Data Source: [Listing 16.2.6.1](#)

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/TABLE/T14020201.SAS EXECUTED: 19AUG2012 15:43

Table 14.2.2.1
Mood and Physical Symptoms Scale - Summary by Product Group Over Time

Scale Item	Minutes Post Admin.		[UB] Subject - specific UB Cigarette	[1] Camel SNUS
Poor Concentration	Pre 0	n	17	16
		Mean (SD)	1.6 (0.87)	1.1 (0.34)
		Median	1.0	1.0
		Min, Max	1, 4	1, 2
	5'	n	17	16
		Mean (SD)	1.1 (0.33)	1.1 (0.34)
		Median	1.0	1.0
		Min, Max	1, 2	1, 2
	15'	n	17	16
		Mean (SD)	1.1 (0.24)	1.1 (0.25)
		Median	1.0	1.0
		Min, Max	1, 2	1, 2
	30'	n	17	16
		Mean (SD)	1.1 (0.24)	1.1 (0.50)
		Median	1.0	1.0
		Min, Max	1, 2	1, 3
	45'	n	17	16
		Mean (SD)	1.1 (0.33)	1.2 (0.54)
		Median	1.0	1.0
		Min, Max	1, 2	1, 3
	60'	n	17	16
		Mean (SD)	1.1 (0.24)	1.2 (0.54)
		Median	1.0	1.0
		Min, Max	1, 2	1, 3

(b) (4)

Data Source: [Listing 16.2.6.1](#)

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/TABLE/T14020201.SAS EXECUTED: 19AUG2012 15:43

Table 14.2.2.1
Mood and Physical Symptoms Scale - Summary by Product Group Over Time

Scale Item	Minutes Post Admin.		[UB] Subject - specific UB Cigarette	[1] Camel SNUS
Poor Concentration	90'	n	17	16
		Mean (SD)	1.1 (0.33)	1.2 (0.54)
		Median	1.0	1.0
		Min, Max	1, 2	1, 3
	120'	n	17	16
		Mean (SD)	1.1 (0.33)	1.1 (0.34)
		Median	1.0	1.0
		Min, Max	1, 2	1, 2
	150'	n	17	16
		Mean (SD)	1.2 (0.75)	1.2 (0.54)
		Median	1.0	1.0
		Min, Max	1, 4	1, 3
	180'	n	17	16
		Mean (SD)	1.3 (0.77)	1.3 (0.77)
		Median	1.0	1.0
		Min, Max	1, 4	1, 4

(b) (4)

Data Source: [Listing 16.2.6.1](#)

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/TABLE/T14020201.SAS EXECUTED: 19AUG2012 15:43

Table 14.2.2.1
Mood and Physical Symptoms Scale - Summary by Product Group Over Time

Scale Item	Minutes Post Admin.		[UB] Subject - specific UB Cigarette	[1] Camel SNUS
Current Urge to Smoke	Pre 0	n	17	16
		Mean (SD)	3.5 (1.07)	3.4 (1.20)
		Median	4.0	3.5
		Min, Max	2, 5	1, 5
	5'	n	17	16
		Mean (SD)	0.7 (0.99)	2.6 (1.41)
		Median	0.0	2.5
		Min, Max	0, 3	0, 5
	15'	n	17	16
		Mean (SD)	0.5 (0.80)	2.1 (1.34)
		Median	0.0	2.0
		Min, Max	0, 2	0, 5
	30'	n	17	16
		Mean (SD)	0.9 (0.75)	1.9 (1.26)
		Median	1.0	2.0
		Min, Max	0, 2	0, 4
	45'	n	17	16
		Mean (SD)	1.2 (0.66)	1.9 (1.06)
		Median	1.0	2.0
		Min, Max	0, 2	0, 4
	60'	n	17	16
		Mean (SD)	1.6 (0.70)	2.1 (0.85)
		Median	2.0	2.0
		Min, Max	1, 3	1, 4

(b) (4)

Data Source: [Listing 16.2.6.1](#)

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/TABLE/T14020201.SAS EXECUTED: 19AUG2012 15:43

Table 14.2.2.1
Mood and Physical Symptoms Scale - Summary by Product Group Over Time

Scale Item	Minutes Post Admin.		[UB] Subject - specific UB Cigarette	[1] Camel SNUS
Current Urge to Smoke	90'	n	17	16
		Mean (SD)	1.9 (0.86)	2.3 (0.93)
		Median	2.0	2.0
		Min, Max	1, 4	1, 4
	120'	n	17	16
		Mean (SD)	2.5 (0.87)	2.5 (0.97)
		Median	2.0	2.0
		Min, Max	1, 4	1, 4
	150'	n	17	16
		Mean (SD)	2.6 (1.00)	3.0 (1.15)
		Median	2.0	3.0
		Min, Max	1, 4	1, 5
	180'	n	17	16
		Mean (SD)	2.9 (0.97)	3.2 (1.17)
		Median	3.0	3.0
		Min, Max	2, 5	1, 5

(b) (4)

Data Source: [Listing 16.2.6.1](#)

Table 14.2.2.2
Mood and Physical Symptoms Scale - Summary of Paired t-tests

(b) (4)



Table 14.2.2.2

(b) (4)



Table 14.2.2.2
Mood and Physical Symptoms Scale - Summary of Paired t-tests

(b) (4)



Table 14.2.2.2
Mood and Physical Symptoms Scale - Summary of Paired t-tests

(b) (4)



Table 14.2.2.2
Mood and Physical Symptoms Scale - Summary of Paired t-tests

(b) (4)



Table 14.2.2.2
Mood and Physical Symptoms Scale - Summary of Paired t-tests

(b) (4)



Table 14.2.2.2
Mood and Physical Symptoms Scale - Summary of Paired t-tests

(b) (4)



Figure 14.3.1
Individual Mood and Physical Symptoms Scale Items vs Time
All Randomized Subjects

(b) (4)



Figure 14.3.1
Individual Mood and Physical Symptoms Scale Items vs Time
All Randomized Subjects

(b) (4)



Figure 14.3.1
Individual Mood and Physical Symptoms Scale Items vs Time
All Randomized Subjects

(b) (4)



Figure 14.3.1
Individual Mood and Physical Symptoms Scale Items vs Time
All Randomized Subjects

(b) (4)



Figure 14.3.1
Individual Mood and Physical Symptoms Scale Items vs Time
All Randomized Subjects

(b) (4)



Figure 14.3.1
Individual Mood and Physical Symptoms Scale Items vs Time
All Randomized Subjects

(b) (4)



Figure 14.3.1
Individual Mood and Physical Symptoms Scale Items vs Time
All Randomized Subjects

(b) (4)



14.3 Safety Data

14.3.1 Displays of Adverse Events

Table Number	Table Title
14.3.1	Adverse Events - Number and Percentage of Subjects by System Organ Class, Preferred Term, and Product Group

Table 14.3.1
Adverse Events - Number and Percentage of Subjects
by System Organ Class, Preferred Term, and Product Group

System Organ Class {1} Preferred Term {1}	[UB] Subject-specific UB Cigarette (N=17)	[1] Camel SNUS (N=16)	(b) (4)
Number of subjects with at least 1 Adverse Event	0	4 (25.0%)	
Blood and lymphatic system disorders	0	0	
Anaemia	0	0	
Gastrointestinal disorders	0	1 (6.3%)	
Hiccups	0	0	
Throat irritation	0	1 (6.3%)	
Injury, poisoning and procedural complications	0	1 (6.3%)	
Fall	0	1 (6.3%)	
Nervous system disorders	0	1 (6.3%)	
Dizziness	0	0	
Headache	0	1 (6.3%)	
Respiratory, thoracic and mediastinal disorders	0	1 (6.3%)	
Nasal congestion	0	1 (6.3%)	

Data Source: [Listing 16.2.7.1](#)

Note: Subjects may have reported more than one event per system organ class or preferred term. Adverse events are temporally attributed to the last product received prior to reporting the event.

{1} From the MedDRA dictionary, version 14.1

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Table 14.3.1
Adverse Events - Number and Percentage of Subjects
by System Organ Class, Preferred Term, and Product Group

System Organ Class {1} Preferred Term {1}	[UB] Subject-specific		[1] Camel SNUS (N=16)	(b) (4)
	UB Cigarette (N=17)			
Skin and subcutaneous tissue disorders	0	0		
Skin laceration	0	0		

Data Source: [Listing 16.2.7.1](#)

Note: Subjects may have reported more than one event per system organ class or preferred term. Adverse events are temporally attributed to the last product received prior to reporting the event.

{1} From the MedDRA dictionary, version 14.1

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/TABLE/T14030100.SAS EXECUTED: 05SEP2012 12:41

14.3.2 Listings of Deaths, Other Serious and Significant Adverse Events

No deaths or other SAEs occurred during this study (Appendix 16.2.7, [Listing 16.2.7.2](#)).

14.3.3 Narratives of Deaths, Other Serious and Certain Other Significant Adverse Events

Not applicable; there were no deaths, other SAEs, or other significant AEs during this study.

14.3.4 Laboratory Data

Laboratory data were provided in listing format only. By-subject listings are provided in Appendix 16.2.8 as follows: complete blood count values are provided in [Listing 16.2.8.1](#); comprehensive metabolic profile, triglycerides, and total cholesterol values are provided in [Listing 16.2.8.2](#); and urinalysis values are provided in [Listing 16.2.8.3](#).

14.3.5 Vital Sign Data

Vital sign data were provided in listing format only. By-subject listings of systolic and diastolic blood pressure, oral temperature, heart rate, height, and weight measurements are provided in Appendix 16.2.8, [Listing 16.2.9](#).

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16. APPENDICES

16.1 Study Information

16.1.1 Protocol and Protocol Amendments

The study protocol (Version 1.0 dated 22 July 2011) and administrative letter (dated 24 August 2011) are provided on the following pages.

CLINICAL STUDY PROTOCOL

Study Title: Assessment of Smokers' Nicotine Uptake and Urge to Smoke After Use of Smokeless Tobacco Products

Protocol Number: CSD1101

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Protocol Version and Date: Protocol Version 1.0, 22 July 2011

Good Clinical Practice Statement

This clinical investigation will be performed in compliance with the protocol, Good Clinical Practice (GCP) as set forth in the International Conference on Harmonization (ICH) Guideline for GCP (1996), and the Declaration of Helsinki (2008).

Confidentiality Statement

This document contains information which is the confidential and proprietary property of R.J. Reynolds Tobacco Company. Any use, distribution, or disclosure without the prior written consent of R.J. Reynolds Tobacco Company is strictly prohibited except to the extent required under applicable laws or regulations. Persons to whom the information is disclosed must be informed that the information is confidential and may not be further disclosed by them.

SPONSOR SIGNATURE PAGE

This clinical study protocol was subject to critical review and has been approved by the Sponsor. The following personnel contributed to writing and/or approving this protocol:


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PROTOCOL SYNOPSIS

Study Title:	Assessment of Smokers' Nicotine Uptake and Urge to Smoke After Use of Smokeless Tobacco Products
Protocol Number:	CSD1101
Principal Investigator/ Study Center:	Gregory P. Tarleton, PharmD, MD Bellomy Research 4305 Enterprise Drive, Suite E Winston-Salem, North Carolina 27106
Study Objectives:	<p>The objectives of this study are to assess the following after a 12-hour tobacco and nicotine abstinence:</p> <ul style="list-style-type: none">• Nicotine uptake in blood over a 3-hour period with respect to in-clinic product administration.• Tobacco abstinence symptoms over a 3-hour period with respect to in-clinic product administration.
Study Population:	Generally healthy males and females between 21 and 55 years of age (inclusive) who self-report smoking 10 to 30 cigarettes per day for at least 6 months prior to screening.
Number of Subjects Planned:	Up to 20 subjects are planned for enrollment and randomization to have at least 16 subjects complete the study.
Study Design:	<p>This is a single-center, randomized, open-label, crossover study designed to evaluate serum nicotine uptake and tobacco abstinence symptoms following administration of a single unit each of four smokeless tobacco products (STPs), including Camel SNUS and (b) (4) and usual brand (UB) cigarettes in current smokers in generally good health. Subjects will abstain from all tobacco and nicotine use for at least 12 hours prior to administration of one study product at each of five test visits.</p> <p>Serial blood samples will be collected up to 3 hours post study product administration for measurement of serum nicotine and cotinine concentrations. Questionnaires will be administered during each test visit to assess tobacco abstinence symptoms.</p>
Study Products:	<ul style="list-style-type: none">• Camel SNUS <p>(b) (4)</p>  <ul style="list-style-type: none">•
Duration of Study:	The duration of subject participation from screening through study completion is approximately 10 weeks, including a 30-day screening period and five ambulatory test visits, with 7 to 18 days between visits.

Biomarker and Questionnaire Evaluations:	(b) (4) (b) (4)
Safety Assessments:	Basic safety will be assessed by physical examinations (including oral exams), clinical laboratory testing, vital sign measurements, and evaluation of adverse events (AEs).
Statistical Methods:	(b) (4) (b) (4)

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LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

Abbreviations	Term or Definition
AE	adverse event
ANOVA	analysis of variance
AUC	area under the time-versus-concentration curve up to the last measurable time point
AUC _{adj}	baseline-adjusted AUC (adjusted for pre-existing nicotine from tobacco use prior to the 12-hour abstinence period)
AUC _{adj(STP)}	baseline-adjusted AUC of smokeless tobacco product
AUC _{adj(UB)}	baseline-adjusted AUC of usual brand cigarette
AUC _{ratio}	the ratio of AUC _{adj(STP)} to AUC _{adj(UB)}
CBC	complete blood count
CFR	Code of Federal Regulations
C _{max}	maximum serum concentration
C _{max(adj)}	baseline-adjusted C _{max} (adjusted for pre-existing nicotine from tobacco use prior to the 12-hour abstinence period)
CMP	comprehensive metabolic profile
CS	clinically significant
ECO	expired carbon monoxide
FTND	Fagerström Test for Nicotine Dependence
GCP	Good Clinical Practice
HIV	human immunodeficiency virus
ICH	International Conference on Harmonization
ICF	informed consent form
IRB	Institutional Review Board
IV	intravenous
LFT	liver function test
MedDRA	Medical Dictionary for Regulatory Activities
MPSS	Mood and Physical Symptom Scale
NCS	not clinically significant
PI	Principal Investigator
ppm	parts per million
RJRT	R.J. Reynolds Tobacco Company
SAE	serious adverse event
SAP	Statistical Analysis Plan
SOP	standard operating procedure

(b) (4)

Abbreviations	Term or Definition
STP	smokeless tobacco product
T _{max}	time to maximum serum concentration
TSNA	tobacco-specific nitrosamine
UB	usual brand
US	United States
WHO	World Health Organization

1. INTRODUCTION

The tobacco control community unanimously supports advising current smokers to quit smoking and never smokers not to start smoking. Some public health officials support the use of smokeless tobacco products (STPs) as an alternative strategy to abstinence for smokers who cannot quit or are unwilling to quit smoking (Stratton *et al.*, 2001). STPs provide an alternative that eliminates exposure to certain combustion toxicants in cigarette smoke, such as carbon monoxide. Additionally, some STPs contain lower levels of tobacco-specific nitrosamines (TSNAs) compared to more traditional STPs. In a 2007 study by Hatsukami *et al.*, the dissolvable tobacco pellet Ariva[®] contained the lowest level of TSNAs of the products tested.

Swedish snus, a moist STP, has relatively low levels of many toxicants compared to cigarette smoke. Results from studies of Scandinavian smokeless tobacco (i.e., snus) users indicated no increased risk of oropharyngeal, larynx, stomach, bladder, kidney, lung, or overall cancer compared with non-users (Lee and Hamling, 2009).

A review of health risks of cigarette smoking compared to Swedish snus suggested the risks for lung, oral, and gastric cancer, and cardiovascular diseases associated with Swedish snus use are lower than those associated with smoking (Roth *et al.*, 2005). An expert panel evaluating the relative risks of low nitrosamine-containing STPs (e.g., snus) compared with cigarette smoking estimated the risk of these smokeless products to be 5 to 10% of that of the health risks from smoking (Levy *et al.*, 2004).

R.J. Reynolds Tobacco Company (RJRT) recently introduced Camel SNUS into the United States (US) market. Camel SNUS, designed and manufactured similarly to Swedish snus, has relatively low levels of many tobacco constituents that are considered by some health professionals to potentially cause harm. The use of snus would offer less exposure to those constituents than cigarette smoking.

(b) (4)



Some scientists have suggested that STPs must suppress smoking abstinence symptoms to be a successful alternative to cigarettes (Cobb *et al.*, 2009). Without adequate suppression, smokers may not continue to use reduced toxicant products and consequently may resume exclusive or near-exclusive smoking. Smoking abstinence symptoms include, but are not limited to, restlessness, irritability, anxiety, impaired concentration, depression, increased

appetite, and craving to smoke (Benowitz, 1996). Several validated questionnaires exist to assess tobacco consumers' perception of these symptoms after a period of tobacco abstinence (Hughes and Hatsukami, 1986; Welsch *et al.*, 1999; Shiffman *et al.*, 2000; West and Hajek, 2004; Etter, 2005). A decrease in a smoker's blood nicotine concentration is one factor that contributes to smoking abstinence symptoms.

Ariva was previously shown to partially suppress tobacco abstinence symptoms in smokers following overnight tobacco abstinence (Blank *et al.*, 2008; Cobb *et al.*, 2009; Kotlyar *et al.*, 2007). However, symptoms were suppressed significantly less than after smoking a cigarette, even a cigarette containing very low levels of nicotine. The same studies showed that plasma nicotine levels did not significantly increase above baseline following use of one Ariva pellet. Although the effects of using Ariva were not equal to smoking in those studies, subjects in a different study preferred Ariva over a medicinal nicotine lozenge to assist smoking cessation (Mendoza-Baumgart *et al.*, 2007).

This study will examine the use of Camel SNUS (b) (4) in smokers after a 12-hour tobacco and nicotine abstinence period. Changes in nicotine exposure and tobacco abstinence symptoms following in-clinic administration of one unit of the (b) (4) different STPs or in-clinic smoking of one usual brand (UB) cigarette will be evaluated.

2. STUDY OBJECTIVES

The objectives of this study are to assess the following after a 12-hour tobacco and nicotine abstinence:

- Nicotine uptake in blood over a 3-hour period with respect to in-clinic product administration.
- Tobacco abstinence symptoms over a 3-hour period with respect to in-clinic product administration.

3. STUDY DESIGN

3.1 Overall Study Design and Plan

This is a single-center, randomized, open-label, crossover study designed to evaluate serum nicotine uptake and tobacco abstinence symptoms following administration of (b) (4) different STPs, including Camel SNUS and (b) (4) and UB cigarettes in current smokers in generally good health. Up to 20 subjects are planned for enrollment and randomization to have at least 16 subjects complete the study. The overall study design is presented in [Figure 1](#).

(b) (4)



Note: Subjects will consume a single unit of each study product: usual brand cigarette, (b) (4) (b) (4) and Camel SNUS.

Figure 1: Overall Study Design

(b) (4)



(b) (4)



3.2 Rationale for Study Design and Control Group

This study will evaluate, in five separate test visits, the serum nicotine uptake and tobacco abstinence symptoms experienced by subjects following in-clinic administration of a single Camel SNUS 600 mg pouch (Frost), (b) (4), and UB cigarette after a 12-hour tobacco and nicotine abstinence period.

Usual brand cigarettes are included for comparison since the use of STPs may be considered an alternative to smoking cigarettes.

A crossover design was chosen to minimize variability and the number of subjects needed for evaluation. A 7- to 18-day period between study product administrations was chosen to allow adequate time for rescheduling of test visits, if required.

By necessity, this study is unblinded due to the different visual appearances of the study products.

4. STUDY SAMPLE SELECTION

4.1 Target Population

The study target population will include smokers of combustible, filtered cigarettes who are between 21 and 55 years of age (inclusive), in reasonably good health (as determined by the Principal Investigator [PI]), and self-report daily smoking of 10 to 30 cigarettes for at least 6 months prior to screening.

All subjects who express an interest in quitting smoking (defined as planning a quit attempt within a month of the Screening Visit) will be encouraged to do so, but will be excluded from the study. These subjects will be referred to their primary care providers for advice on quitting smoking. For subjects without a primary care provider, the Investigator will refer to the subjects to a qualified provider.

Some subjects may have chronic health conditions (e.g., hypertension and/or hypercholesterolemia) and may be taking prescription medications for these conditions. Assuming that chronic health conditions are well-controlled and that stable doses of prescription medications are being used, these subjects may be considered for study inclusion at the PI's discretion.

4.2 Inclusion Criteria

Each subject must meet all the following criteria to be enrolled in this study:

1. Able to comprehend and willing to sign an informed consent form (ICF).
2. Able to read, comprehend, and complete questionnaires in English.
3. Male or female, age 21 to 55 years, inclusive.
4. Generally healthy based on screening assessments, as judged by the PI.
5. Primary tobacco use is smoking cigarettes.
6. Smokes combustible, filtered cigarettes, 83 mm to 100 mm length, menthol or non-menthol.
7. Self-reported daily use of 10 to 30 cigarettes at the Screening Visit.
8. Willing to abstain from tobacco and nicotine use for at least 12 hours prior to each study product administration.
9. Females must be willing to use a form of contraception acceptable to the Investigator from the time of signing consent until study discharge or be surgically sterile for at least 90 days prior to enrollment.

4.3 Exclusion Criteria

Subjects who meet any of the following criteria will be excluded from the study:

1. Postponing a decision to quit smoking (defined as planning a quit attempt within a month of the Screening Visit) to participate in this study.

2. Employed by a tobacco company, a sub-contractor of a tobacco company, or handles tobacco as part of their job.
3. Current oral lesion(s) at the Screening Visit.
4. A history of clinically significant (CS) heart disease, kidney disease, asthma or any other lung disease, diabetes, liver disease, neurological disease, or psychiatric disorder, as determined by the Investigator.
5. Self-reports human immunodeficiency virus (HIV), Hepatitis B, or Hepatitis C infection.
6. Current diagnosis of peptic ulcers or irritable bowel syndrome at the Screening Visit.
7. Uncontrolled hypertension defined as a systolic blood pressure of ≥ 200 mmHg or a diastolic blood pressure of ≥ 100 mmHg.
8. Hemophilia or any other bleeding disorders.
9. Clotting disorders with concomitant use of anticoagulants (see [Section 9 "Concomitant Medications"](#)).
10. Given a whole blood donation within 8 weeks (56 days) prior to the Screening Visit.
11. Weighs < 110 pounds.
12. Poor peripheral venous access (at Screening Visit or Test Visit 1).
13. Hemoglobin level is < 12.5 g/dL at the Screening Visit.
14. Elevated liver function test (LFT) results > 2 times the upper limits of normal on the clinical laboratory tests obtained at the Screening Visit.
15. Serum creatinine level > 1.6 mg/dL on the clinical laboratory tests obtained at the Screening Visit.
16. Any laboratory value (on clinical laboratory tests obtained at the Screening Visit) outside the laboratory reference range, considered by the PI to be clinically significant (CS).
17. ECO level is < 15 parts per million (ppm) or > 100 ppm at the Screening Visit, measured between 12 p.m. and 6 p.m.
18. ECO level is > 12 ppm at check-in of Test Visit 1.
19. Use of cigars or electronic cigarette devices within 30 days prior to the Screening Visit.
20. Use of any type of smokeless tobacco or non-tobacco nicotine-containing product(s) within 30 days of the Screening Visit.
21. Use of illegal substances within 30 days of the Screening Visit
22. Use of any medication or supplement that aids smoking cessation, including varenicline (Chantix[®]) and bupropion (Wellbutrin[®], Zyban[®]), within 30 days of the Screening Visit.
23. Use of lobelia extract within 30 days of the Screening Visit.
24. Self-reports a history of illegal intravenous (IV) drug use.
25. Self-reports drinking more than 14 servings of alcoholic beverages per week (1 serving = 12 oz of beer, 6 oz of wine, or 1 oz of liquor).
26. A positive urine drug screen without disclosure of corresponding prescribed concomitant medication(s), at the Screening Visit or check-in at Test Visit 1.
27. Females with a positive urine pregnancy test.

28. Females that have given birth within the past 12 months prior to the Screening Visit or are currently breastfeeding.
29. Females ≥ 35 years of age currently using systemic, estrogen-containing contraception or hormone replacement therapy.
30. Deemed by the PI to be unsuitable for the study due to a medical condition, disease, concomitant medication or any other reason not previously listed that in the opinion of the PI would make the subject unsuitable in this clinical trial.

4.4 Subject Withdrawal

Subjects will be informed that they have the right to withdraw from the study at any time and for any reason. The PI may withdraw a subject from the study for any of the following reasons:

- Change in status with respect to an inclusion/exclusion criterion that is clinically relevant and/or could affect subject safety;
- Noncompliance with protocol requirements;
- Adverse event(s);
- Pregnancy;
- Inability to communicate and/or unwillingness to cooperate with the Investigator; or
- Other (the reason must be specified).

The date of subject withdrawal and the reason for discontinuation will be documented. If a subject's study participation is terminated (voluntarily or by the PI) after completion of Test Visit 1, the subject will be asked to return for a standard physical exam (to include clinical laboratory tests) as soon as convenient, but not later than 15 days following notification of withdrawal from the study. All discontinuations due to AEs will be followed until the AEs have stabilized as judged by the PI.

The entire study may be discontinued at the combined discretion of the Sponsor and PI based on the occurrence of the following:

- AEs unknown to date with respect to their nature, severity, and duration;
- Increased frequency and/or severity and/or duration of known AEs;
- Medical or ethical reason affecting the continued performance of the study; or
- Unforeseen difficulties in the recruitment of subjects.

5. STUDY PRODUCTS

5.1 Description of Study Products

The (b) (4) STPs being evaluated in this study (Camel SNUS [600 mg pouch, Frost variety], (b) (4)) are intended to be used without the need to spit.

Camel SNUS is a pouched, moist snuff product composed of pasteurized tobacco with a low sodium and moisture content. Camel SNUS is available commercially.

(b) (4)

All smokeless tobacco study products will be provided to subjects. Additional product details are described in the Investigational Product Brochure.

The effects of UB cigarettes will also be studied for comparison with results from STP administration. Subjects will provide their own UB cigarettes for use during study participation.

5.2 Provisioning, Packaging, and Labeling

RJRT will supply the required quantities of smokeless tobacco study products to the study site. Study products shall be packaged to prevent contamination and deterioration during transport and storage. Labeling of all products shall be compliant with applicable regulatory requirements.

5.3 Storage, Dispensation, and Disposal

Smokeless tobacco study products will be stored at the study site in a secure area. Camel SNUS will be stored at $\leq 40^{\circ}\text{F}$ ($\leq 4^{\circ}\text{C}$). (b) (4)

The PI will be responsible for insuring supervision of the storage and allocation of smokeless tobacco study products and maintaining accurate records for the dispensation of study products. Study product accountability logs shall include, but will not be limited to, the following information:

- The total amounts of study products provided for the study and the date(s) on which these were received from the Sponsor.
- The amount of study product dispensed to each subject and the date dispensed.
- The amount of study product that is returned to the Sponsor or destroyed at the end of the study.

After completion of the clinical phase and per Sponsor discretion, all unused smokeless tobacco study products will either be returned to RJRT or destroyed on site per the study site's procedure. Dispensation of study products must be accounted for on study product accountability logs.

Study monitors will review study product records to verify the following:

- Acceptable storage conditions and sufficient supplies.
- Dispensation to only qualified subjects and in protocol-specified quantities.
- Adequate control and documentation of study product dispensation and return.
- Compliance of study product dispensation with applicable regulatory requirements and in accordance with the Sponsor's and study site's procedures.

5.4 Sampling of Study Product Prior to Each Test Visit

At the conclusion of Test Visits 1, 2, 3, and 4, subjects will be required to sample one unit of the STP to which they will be randomized for the next test visit. Subjects will be requested to use the smokeless product according to the product use instructions provided in [Section 5.7](#). After sampling, subjects will be asked to reconfirm their consent to participate in the study.

Note: Subjects who are not eligible to participate in test visit procedures (e.g., due to excessive ECO levels) will sample the study product randomly assigned for the test visit to be rescheduled. Subjects who find the study product to be unacceptable will not be rescheduled for the test visit and will be dismissed from the study. Subjects who determine the study product to be acceptable and reconfirm consent to participate will be rescheduled for the test visit, as appropriate.

5.5 Study Product Administration

5.5.1 Usual Brand Cigarettes

At the Screening Visit, each subject will provide study staff with one pack of his/her UB cigarette. The pack will be photocopied to capture brand-specific descriptor information and returned to the subject.

At Test Visit 1, subjects will provide the study staff with one UB cigarette. The UB cigarette provided will be confirmed as the same UB documented at the Screening Visit. The subject's UB cigarette will be dispensed to him/her to smoke during Test Visit 1. Subjects will be asked to smoke the cigarette according to their usual pattern. In-clinic smoking duration will be timed. Each subject will smoke one UB cigarette at Test Visit 1.

5.5.2 Smokeless Tobacco Products

At Test Visits 2, 3, 4, and 5, subjects will consume one unit of assigned STP according to instructions (see [Section 5.7 “Product Use Instructions”](#)). The order of STP administration will be determined by a randomization schedule.

Consumption of all smokeless tobacco study products during test visits will be timed to determine duration of use.

5.6 Method of Assigning Subjects to Study Products

Randomization to the order of STPs will be based on a Williams Design.

5.7 Product Use Instructions

Instructions for STP use will be provided to each subject. Subjects will be asked to follow the instructions for in-clinic product administration.

Smokeless Camel SNUS use instructions:

- Place the pouch between your upper or lower lip and gum.
- Leave the pouch in place for a minimum of 15 minutes.
- Do NOT leave the pouch in place for more than 30 minutes.
- Occasionally move the pouch to a different location between your upper or lower lip and gum (suggested, but not required).
- Do not chew the product.
- Do not spit during or after use (during the test visit).
- Do not eat or drink while using the product.
- Do not swallow the product.

(b) (4)

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

5.8 Cigarette Use Logs

At Screening and Test Visits 1 through 4, subjects will be provided with blank, 7-day Cigarette Use Logs to record at-home cigarette use. Subjects will record the number of UB cigarettes smoked per day and the time their last cigarette was extinguished the evening before each test visit.

Subjects will return completed Cigarette Use Logs at each test visit.

5.9 Assessment of Compliance

In-clinic study product consumption will occur under the direct supervision of study site staff. (b) (4)

Compliance with consumption of Camel SNUS will be confirmed by collection of used snus pouches (and subsequent disposal) by study site staff.

Subjects who use any tobacco- or nicotine-containing products other than their UB cigarettes or their assigned study product during study participation will be dismissed from the study.

During each test visit, tobacco and nicotine product use will be determined by asking subjects variations of the questions listed below:

1. Have you smoked any cigarettes other than your UB since your last visit?
2. Have you used any nicotine replacement products since your last visit?
3. Have you used any tobacco products, other than cigarettes, since your last visit?

Prior to each test visit, ECO will be measured to determine subject eligibility to undergo visit procedures. Subjects must register an ECO ≤ 12 ppm to participate in the test visit. Subjects with an ECO > 12 ppm at Test Visit 1 will not be eligible for study enrollment. Enrolled subjects with an ECO > 12 ppm at Test Visits 2, 3, 4, or 5 will not be eligible to participate in the test visit procedures, but will be given the opportunity to reschedule the test visit within the scheduling window (see [Section 6.2 "Schedule of Visits"](#)). Any subject with an ECO > 12 ppm at any two test visits after Test Visit 1 will be compensated and dismissed from the study.

6. STUDY PROCEDURES

6.1 Study Procedures By Visit

The schedule of visit study procedures is provided in [Table 1](#).

Table 1: Schedule of Events

Evaluation	Screening Visit (up to 30 days)	Test Visit 1	Test Visit 2	Test Visit 3	Test Visit 4	Test Visit 5
Informed Consent	X					
Inclusion/Exclusion Criteria	X	X				
Demographics/Height/Weight	X					
Blood Pressure ¹	X	X	X X X			X
Pulse Rate ¹	X	X				X
Body Temperature (oral)	X	X				X
Urine Drug Screen	X	X				
Urine Pregnancy Screen (females only)	X	X	X X X			X
Clinical Laboratory Tests ²	X					X
Physical Examination	X					X
Oral Examination	X					X
Medical History	X	X ³	X ³	X ³	X ³	X ³
Document Contraception Method (females only)	X					
Fagerström Test for Nicotine Dependence	X					
Expired Carbon Monoxide	X ⁴	X	X X X			X
UB Cigarette Pack (photocopy and record description information)	X					
Record Time of Last Cigarette Prior to Visit ⁵	X	X	X X X			X
Tobacco/Nicotine Abstinence Instructions	X	X	X X X			
Cigarette Use Log ⁶	X	X	X X X			X
Enrollment & Randomization		X ⁷				
Intravenous Catheter ⁸		X	X X X			X
Confirm UB Cigarette		X	X X X			X
Collect One UB Cigarette		X				
Assess Compliance with Tobacco/Nicotine Product Restrictions		X	X X X			X
Study Product Administration/ Instructions for STP Use/ Record Duration of Use		X	X X X			X
Nicotine/Cotinine Blood Samples ⁹		X	X X X			X
Mood and Physical Symptoms Scale ¹⁰	X	X	X X X			X
Adverse Event Assessment		X	X X X			X
Concomitant Medication Assessment	X	X	X X X			X
Sampling of Assigned Study Product for Next Visit/ Instructions for STP Use		X	X X X			
Exit Questionnaire						X
Discharge Subject from Study						X

1. Obtain blood pressure and pulse after subject has remained seated for at least 5 minutes.

2. Includes complete blood count (CBC), comprehensive metabolic profile (CMP), urinalysis, triglycerides, and total cholesterol.

3. Update findings from medical history documented at screening.

4. Obtain the ECO level between 12 p.m. and 6 p.m.

5. At the screening visit, the estimated time will be recorded; at test visits, the actual time from the Cigarette Use Log will be recorded.

6. Dispense blank logs at Screening Visit and Test Visits 1, 2, 3, and 4. Collect completed logs at Test Visits 1, 2, 3, 4, and 5.

7. Discharge subjects who are not enrolled and return previously collected UB cigarette.

8. Insert catheter prior to administration of study product; remove catheter after collection of scheduled blood samples.

9. Samples collected at pre-0, 0, 3, 5, 7.5, 10, 15, 20, 30, 45, 60, 75, 90, 120, 150, and 180 minutes with respect to in-clinic study product administration.

10. At each test visit, questionnaire administered prior to attempting catheter placement and at 5, 15, 30, 45, 60, 90, 120, 150, and 180 minutes with respect to in-clinic study product administration.

6.2 Schedule of Visits

Test Visit 1 will be completed no later than 30 days following the Screening Visit. After Test Visit 1, each subsequent test visit will be completed a minimum of 7 calendar days and no more than 18 calendar days after the preceding completed test visit.

6.2.1 Screening Visit Procedures

- Obtain signed, written informed consent for study participation.
- Perform urine pregnancy test (females only).
- Perform standard physical exam including an oral examination.
- Obtain body temperature (orally).
- Obtain blood pressure and pulse rate after subject has been seated for at least 5 minutes.
- Record medical history and concomitant medication use.
- Document contraception method (females only). Contraception method must be approved by the Investigator. Examples of acceptable forms of contraception may include oral, injectable, or implantable contraceptives; intrauterine devices; and/or barrier methods.
- Obtain demographic data (obtain for all subjects/screen fails).
- Obtain height and weight (obtain for all subjects/screen fails).
- Record approximate time last cigarette was extinguished.
- Obtain ECO level between 12 p.m. and 6 p.m.
- Perform urine drug screen.
- Obtain blood and urine samples for clinical laboratory tests.
- Photocopy and record UB cigarette descriptor information (brand name, style, etc.).
- Administer the Fagerström Test for Nicotine Dependence (FTND; [Appendix 1](#)) and MPSS ([Appendix 2](#)) questionnaires.
- Review inclusion and exclusion criteria.
- Provide subjects with Cigarette Use Log and verbal instructions for recording at-home UB cigarette use.
- Provide subjects with instructions for abstaining from all tobacco and nicotine products prior to check-in at Test Visit 1, and remind subjects to not use any tobacco- or nicotine-containing products other than their UB cigarettes or assigned study products during study participation.

6.2.1.1 Subject Eligibility and Test Visit Scheduling

The PI will review all information obtained from Screening Visit procedures including a review of all clinical laboratory results. Subjects who fulfill all the inclusion criteria and none of the exclusion criteria will be eligible to participate the study. Study personnel will contact eligible subjects by phone to schedule Test Visit 1. If the subject is not eligible, for any reason, he/she will be considered a screen failure and will not attend any future test visits. Subjects who screen fail due to CS laboratory test results will be contacted by the PI.

6.2.2 Test Visit 1 Procedures

All Subjects

- Collect completed Cigarette Use Log, and
- Record time (from the Cigarette Use Log) that last cigarette was extinguished.
- Confirm UB descriptor information and collect one UB cigarette.
- Update medical history and concomitant medications.
- Perform urine drug screen (all subjects) and urine pregnancy test (females).
- Obtain ECO level. Subjects' ECO must be ≤ 12 ppm to be enrolled in the study and to continue with Test Visit 1 procedures.
- Assess compliance with nicotine- and tobacco-product restrictions by asking subjects questions to determine use (see [Section 5.9 "Assessment of Compliance"](#)).
- Obtain body temperature (orally).
- Obtain blood pressure and pulse rate after subject has been seated for at least 5 minutes.
- Review inclusion/exclusion criteria for continued eligibility and enroll subject.

Discharged Subjects

- Discharge subjects who are not enrolled and return previously collected UB cigarette.

Enrolled Subjects

- Assess and record AEs.
- Insert IV catheter.
- Administer one UB cigarette for in-clinic use.
- Measure and record length of time cigarette was smoked.
- Collect nicotine/cotinine blood samples at designated times with respect to the start of in-clinic product administration (see [Section 7.3.1 "Blood Sample Collection"](#)).
- Administer MPSS at designated times (see [Section 7.4.2 "Mood and Physical Symptoms Scale"](#)).
- Remove IV catheter.

End of Test Visit 1

- Randomize subject to study product administration order. Administer one unit of the smokeless product to which the subject will be randomized for the next test visit and provide instructions for use (see [Section 5.7 "Product Use Instructions"](#)).
- The subject is free to withdraw at this point if the product is not acceptable. Ensure that the subject reconfirms his/her consent to participate in the study.
- Provide subjects with Cigarette Use Log and verbal instructions for recording at-home UB cigarette use.
- Provide subjects with instructions for abstaining from all tobacco and nicotine products prior to check-in at Test Visit 2, and remind subjects to not use any tobacco- or nicotine-containing products other than their UB cigarettes or assigned study products during study participation.

6.2.3 Test Visit 2 through Test Visit 5 Procedures

- Collect completed Cigarette Use Log.
- Record time (from the Cigarette Use Log) last cigarette was extinguished.
- Confirm UB descriptor information.
- Assess and record AEs.
- Update medical history and concomitant medications.
- Perform urine pregnancy test (females).
- Obtain blood pressure after subject has been seated for at least 5 minutes.
- Obtain ECO level. Subjects' ECO must be ≤ 12 ppm to complete test visit procedures. Subjects with an ECO > 12 ppm may be eligible to reschedule the test visit; see [Section 7.2 "Expired Carbon Monoxide"](#).
- Assess compliance with nicotine- and tobacco-product restrictions by asking subjects questions to determine use (see [Section 5.9 "Assessment of Compliance"](#)).
- Insert IV catheter.
- Provide instructions for STP use (see [Section 5.7 "Product Use Instructions"](#)).
- Administer one unit of randomized study product for in-clinic use.
- Measure and record length of time product was used.
- Collect nicotine/cotinine blood samples at designated times with respect to the start of in-clinic product administration (see [Section 7.3.1 "Blood Sample Collection"](#)).
- Administer MPSS at designated times (see [Section 7.4.2 "Mood and Physical Symptoms Scale"](#)).
- Remove IV catheter.

End of Test Visits 2, 3, and 4 only:

- Administer one unit of the smokeless product to which the subject will be randomized for the next test visit and provide instructions for use (see [Section 5.7 "Product Use Instructions"](#)).
- The subject is free to withdraw at this point if the product is not acceptable. Ensure that the subject reconfirms his/her consent to participate in the study.
- Provide subjects with Cigarette Use Log and verbal instructions for recording at-home UB cigarette use.
- Provide subjects with instructions for abstaining from all tobacco and nicotine products prior to check-in at the next test visit, and remind subjects to not use any tobacco- or nicotine-containing products other than their UB cigarettes or assigned study products during study participation.

Test Visit 5 only:

- Perform standard physical exam including vital signs (blood pressure and pulse rate after subject has been seated for at least 5 minutes and oral temperature) and an oral exam.
- Obtain blood and urine samples for clinical laboratory tests.
- Administer Exit Questionnaire ([Appendix 3](#)).
- Discharge subject from study.

6.3 Diet, Fluid, Tobacco, and Activity Control

Subjects will be required to abstain from all tobacco and nicotine use for at least 12 hours prior to each study product administration.

Smoking abstinence will be confirmed by measuring the amount of carbon monoxide in smokers' expired breath at the start of each test visit. Subjects must register an ECO level of ≤ 12 ppm at the start of each test visit to complete study procedures.

From the time subjects sign the ICF until study discharge, subjects must not smoke or otherwise consume any tobacco or nicotine-containing product other than UB cigarettes and study STPs. During each test visit, subjects will also be asked questions (see [Section 5.9 "Assessment of Compliance"](#)) to determine tobacco/nicotine use prior to the visit.

Subjects will not be permitted to make a whole blood donation during the course of the study.

No restrictions will be placed on subjects' usual food, drink, and activity patterns. However, subjects will not be allowed to eat or drink while using study product in-clinic.

6.4 Blood Volume

Total blood sampling volume for the individual subject throughout the duration of the study will not exceed 390 mL (20 mL for clinical laboratory tests and 370 mL for biomarker assessments). For this reason, subjects will not be permitted to make a whole blood donation during the course of the study.

7. STUDY ASSESSMENTS

7.1 Safety Assessments

Safety will be assessed by: monitoring AEs, physical examinations (including an oral exam), clinical laboratory tests, and vital sign measurements.

7.1.1 Adverse Events

Any untoward medical occurrence experienced by a subject after enrollment (at Test Visit 1), whether or not considered study product-related by the Investigator, will be recorded as an AE. Adverse event information will be elicited by indirect questioning using a non-leading question such as, "How have you been feeling this past week?"

Questionnaire responses (i.e., MPSS) will not be used to evaluate or capture AEs.

7.1.2 Physical Examination, Including Oral Examination

Standard physical examinations, including an oral exam, will occur at the Screening Visit and at the end of Test Visit 5 (or early termination). Physical and oral exams will be performed by the PI or sub-investigator. The physical exam will include but will not be limited to: heart, lungs, abdomen, skin, ear, nose, throat, and neck. The oral examination will consist of an oral soft tissue exam for evidence of leukoplakia, other oral keratosis, or oral lesions.

7.1.3 Clinical Laboratory Tests

Clinical laboratory tests will be performed at the Screening Visit and at Test Visit 5 (or early termination). The PI will notify the Sponsor if repeat laboratory testing is needed. Clinical laboratory tests will include the following:

- **Complete blood count (CBC):** hematocrit, hemoglobin, mean corpuscular hemoglobin, mean corpuscular hemoglobin concentration, mean corpuscular volume, mean platelet volume, platelet count, red blood cell distribution width, red blood cell count, and white blood cell count
- **Comprehensive metabolic profile (CMP):** albumin, alkaline phosphatase, alanine aminotransferase, aspartate aminotransferase, blood urea nitrogen, calcium, chloride, carbon dioxide, creatinine, glucose, potassium, sodium, total bilirubin, and total protein
- **Urinalysis (macroscopic):** urine color and appearance, urine pH, urine specific gravity, urine bilirubin, urine glucose, urine ketones, urine leukocytes, urine nitrite, urine protein, occult blood, and urobilinogen
- **Triglycerides**
- **Total Cholesterol**

For the entire study, a total of approximately 20 mL will be drawn for clinical laboratory tests (approximately 10 mL at both the Screening Visit and completion of Test Visit 5 [or early termination]). Blood samples collected for clinical laboratory test may be drawn by venipuncture (e.g., Screening Visit or early termination) or drawn from the IV catheter (e.g., completion of Test Visit 5).

All clinical laboratory results obtained from subjects at the Screening Visit will be reviewed by the PI to determine eligibility for study participation. All results will be re-assessed at check-in of Test Visit 1 to determine continued eligibility and enrollment into the study.

Clinical laboratory results that are outside the normal ranges listed will be assessed by the PI. All abnormal results will be judged CS or not CS (NCS). All CS results will be exclusionary for participation in the study.

- Hemoglobin levels must be ≥ 12.5 g/dL at the Screening Visit for subjects to be eligible for enrollment. Clinically significant hemoglobin levels at Test Visit 5 (or early termination) will be recorded as AEs.
- Subjects with an LFT > 2 times the upper limit of normal range will not be enrolled in the study.
- Subjects with a serum creatinine level > 1.6 mg/dL will not be enrolled in the study.
- Subjects with any other laboratory results judged to be CS by the PI will not be enrolled in the study.
- A urine drug screen will be performed at the Screening Visit and Test Visit 1. Subjects with positive urine drug screens without disclosure of corresponding prescribed concomitant medication(s) will not be enrolled.
- Urine pregnancy tests will be performed at the Screening Visit and at each test visit for all females. Females must test negative for pregnancy to be eligible for enrollment and at each subsequent test visit to continue in the study.

7.1.4 Vital Signs

At the Screening Visit and check-in for Test Visits 1 through 5 (or early termination), blood pressure will be measured after subjects have been seated for at least 5 minutes. Systolic blood pressure must be < 200 mmHg and diastolic blood pressure must be < 100 mmHg to be eligible for enrollment and at each subsequent test visit to continue in the study. If appropriate, additional blood pressure measurements may be taken at the discretion of the Investigator.

At the Screening Visit, Test Visit 1, and at the end of Test Visit 5 (or early termination), pulse rate will be measured after subjects have been seated for at least 5 minutes.

Body temperature (oral) will be measured at the Screening Visit, Test Visit 1, and at the end of Test Visit 5 (or early termination).

7.2 Expired Carbon Monoxide

At the Screening Visit, ECO will be measured between 12 p.m. and 6 p.m. Expired carbon monoxide levels must be not less than 15 ppm and not more than 100 ppm to be eligible for enrollment.

At check-in of each test visit, ECO will be measured to confirm smoking abstinence and to determine subject eligibility to undergo visit procedures. Subjects must register an ECO ≤ 12 ppm to participate in the test visit.

Subjects with an ECO > 12 ppm at Test Visit 1 will not be eligible for study enrollment. With the exception of study product sampling (see [Section 5.4 “Sampling of Study Product Prior to Each Test Visit”](#)), enrolled subjects with an ECO > 12 ppm at Test Visits 2, 3, 4, or 5 will not be eligible to participate in the test visit procedures that day; these subjects will be given the opportunity to reschedule the test visit within the scheduling window (see [Section 6.2 “Schedule of Visits”](#)). Any subject with an ECO > 12 ppm at any two test visits after Test Visit 1 will be compensated and dismissed from the study.

Additional ECO measurements may be taken at the discretion of the Investigator.

7.3 Biomarker Assessments

7.3.1 Blood Sample Collection

Blood samples will be collected by insertion and maintenance of an IV catheter. If venous access is unable to be started or maintained by a catheter, a blood sample may be drawn by venipuncture. At least one blood sample should be drawn for each subject before the start of product use, even if the IV catheter is not able to be placed successfully. Intravenous access will be maintained by injection of approximately 0.1cc heparin into the port following collection of each blood sample. Approximately 1cc of fluid (containing blood and localized heparin) will be drawn from the port prior to blood sample collection to prevent contamination of the sample with heparin.

Blood samples will be collected with respect to the start time of in-clinic product administration at: pre-0, 0, 3, 5, 7.5, 10, 15, 20, 30, 45, 60, 75, 90, 120, 150, and 180 minutes. Sample collection at 0, 3, 5, 7.5, 10, 15, 20, 30, 45, 60, 75, and 90 minutes will occur ± 30 seconds of each scheduled time point. Sample collection at 120, 150, and 180 minutes will occur ± 2 minutes of each scheduled time point. The blood collection that coincides with the start of in-clinic product administration (0 minutes) may occur up to 1 minute prior to product administration, but not after product administration.

In each test session, the total volume of blood to be drawn for biomarker assessments is approximately 74 mL. For the entire study, a total of approximately 370 mL will be drawn. Totals are based on 16 blood draws of 3.5 mL, 1 mL for removal of heparin from the port prior to each blood draw, and 2 mL for determination of successful catheter placement.

7.3.2 Blood Sample Processing

Blood samples will be collected in serum separator tubes and will be processed no more than 8 hours after collection. Samples will be centrifuged at approximately 3000 rpm for 20 minutes (\pm 30 seconds) at approximately 8°C. Serum will be aliquoted, frozen at approximately -70°C, and shipped to a contract bioanalytical laboratory for analysis of nicotine and cotinine concentrations.

7.3.3 Biomarker Variables

(b) (4)



7.4 Questionnaires

7.4.1 Fagerström Test for Nicotine Dependence

The FTND ([Heatherton et al., 1991](#)) ([Appendix 1](#)) will be administered only at the Screening Visit. This six-item questionnaire is designed to estimate the degree of nicotine dependence in tobacco smokers.

7.4.2 Mood and Physical Symptoms Scale

The MPSS ([West and Hajek, 2004](#)) ([Appendix 2](#)) will be completed by subjects once at the Screening Visit and 10 times during each test visit. The first MPSS questionnaire administered at each test visit will be completed prior to attempting IV catheter insertion. All other MPSS administrations will occur with respect to the start time of in-clinic product administration. Subjects must start the MPSS at 5, 15, 30, 45, 60, 90, 120, 150, and 180 minutes following the start time of in-clinic product administration. At the 5, 15, 30, and 45 minute time points, the MPSS should be started by the subject within 1 minute of the designated time of questionnaire administration (e.g., 5 to 6 minutes at the 5-minute time point). At the 60, 90, and 120 minute time points, the MPSS should be started by the subject

within 2 minutes following the designated time of questionnaire administration (e.g., 60–62 minutes at the 60-minute time point). At the 150 and 180 minute time points, the MPSS should be started by the subject within 5 minutes following the designated time of questionnaire administration (e.g., 150–155 minutes at the 150-minute time point).

7.4.3 Exit Questionnaire

An Exit Questionnaire ([Appendix 3](#)) will be administered at Test Visit 5 just before study discharge. Subjects will be asked about their experiences during study participation.

8. ADVERSE EVENTS

Any untoward medical occurrence experienced by a subject prior to study enrollment will be recorded as an intercurrent illness and will be considered an update in the subject's medical history. Any untoward medical occurrence experienced by a subject after enrollment (at Test Visit 1) until completion of the study, whether or not considered related to the use of study product by the Investigator, will be recorded as an AE.

All AEs will be coded using the Medical Dictionary for Regulatory Activities (MedDRA), Version 13.1 or higher.

Questionnaire responses will not be used to evaluate or capture AEs.

8.1 Definition of Adverse Events

An AE (also referred to as an adverse experience) is defined as any untoward medical occurrence reported throughout the course of the study following subject enrollment (at Test Visit 1). AEs can be any unfavorable and unintended sign (e.g., abnormal laboratory finding), symptom, or disease, with any judgment about causality.

All AEs, whether volunteered, elicited, or noted on physical examination, will be recorded throughout the study.

An adverse reaction is any AE caused by a study product (i.e., UB cigarette, Camel SNUS, (b) (4)). Adverse reactions are a subset of all suspected adverse reactions for which there is reason to conclude that the subject's study product caused the event.

A suspected adverse reaction is any AE for which there is a reasonable possibility that the subject's study product caused the AE. A suspected adverse reaction implies a lesser degree of certainty about causality than adverse reaction, which means any AE caused by the subject's study product.

An AE or suspected adverse reaction is considered unexpected if it is not consistent with the known specificity and severity of side effects listed in the applicable product information, such as the Investigational Product Brochure.

8.2 Severity

The severity of AEs will be categorized as follows:

- **MILD** = experience is minor and does not cause significant discomfort to subject or change in activities of daily living; subject is aware of symptoms, but symptoms are easily tolerated.
- **MODERATE** = experience is an inconvenience or concern to the subject and causes interference with activities of daily living, but the subject is able to continue with activities of daily living.

- **SEVERE** = experience significantly interferes with activities of daily living, and the subject is incapacitated and/or unable to continue with activities of daily living.
- **LIFE-THREATENING** = experience places the subject at immediate risk of death.
- **DEATH** = experience results in the subject's death.

8.3 Relationship

The Investigator will make a determination of the relationship of the AE to the study product using a 5-category system (definite, probable, possible, unlikely, or unrelated) according to the following guidelines:

- **DEFINITE** = an AE that follows a reasonable temporal sequence from use of the study product (including the course following discontinued use of the study material), follows a known or hypothesized cause-effect relationship, and (if appropriate) satisfies the following:
 - positive results obtained in study product sensitivity tests;
 - toxic level of the study product present in blood or other body fluids.
- **PROBABLE** = an AE that follows a reasonable temporal sequence from use of the study product (including the course following discontinued use of the study product) and that can be excluded as being possibly caused by other factors, such as underlying disease, complications, concomitant medications, or concurrent treatment.
- **POSSIBLE** = an AE that follows a reasonable temporal sequence from the use of the study product (including the course following discontinued use of the study product) and that cannot be excluded as being possibly caused by the study product (e.g., existence of similar reports attributed to the suspected study product and/or its analogues; reactions attributable to the pharmacological effect of the study product), although other factors such as underlying disease, complications, concomitant medications, or concurrent treatment are presumable.
- **UNLIKELY** = an AE with an improbable temporal sequence from the use of the study product and can be reasonably explained by other factors, such as underlying disease, complications, concomitant medications, or concurrent treatment.
- **UNRELATED** = an AE that does not follow a reasonable temporal sequence from use of the study product and that can be reasonably explained by other factors, including underlying disease, complications, concomitant medications, or concurrent treatment.

8.4 Serious Adverse Events

8.4.1 Definition of Serious Adverse Events

An AE or suspected adverse reaction is considered a serious adverse event (SAE) if, in the opinion of either the Investigator or Sponsor, it results in any of the following outcomes:

- Death;
- A life-threatening adverse study product experience, i.e., places the subject, in the view of the PI or Sponsor, at immediate risk of death;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect;
- An important medical event that may require medical or surgical intervention to prevent one of the above outcomes.

Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered SAEs when, based upon a appropriate medical judgment, they may jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of study product dependency or study product abuse.

8.4.2 Reporting Serious Adverse Events

Reportable AEs are SAEs that are unexpected. SAEs will be reported by the study site to the Sponsor and the responsible Institutional Review Board (IRB). The Sponsor will be notified in writing (emailed PDF documents are highly preferable to faxed reports) within 24 hours (one working day) of when a reportable SAE is first recognized or reported by contacting:

Sponsor Contacts:

Mitchell F. Stiles, MBA
R.J. Reynolds Tobacco Company
Product Integrity, Research and Development
950 Reynolds Boulevard
Winston-Salem, North Carolina 27105
Telephone: 336-741-2651
Facsimile: 336-741-2841
Email: stilesm@rjrt.com

Bobbette A. Jones, DrPH, RD, CCRP
R.J. Reynolds Tobacco Company
Product Integrity, Research and Development
950 Reynolds Boulevard
Winston-Salem, North Carolina 27105
Telephone: 336-741-7589
Facsimile: 336-741-2640
Email: jonesb6@rjrt.com

Subsequently, a written confirmation or summary of the SAE will be sent to the Sponsor within three working days of the original notification.

The IRB will be notified in writing within 24 hours (one working day) of when a reportable SAE is first recognized or reported. In addition, a copy of the written confirmation or summary of the SAE, as submitted to the Sponsor, will also be submitted to the IRB within three working days of when the SAE is first recognized or reported. The IRB's serious and unexpected adverse experience submission form will be completed and submitted with the copy of the written confirmation or summary of the SAE.

8.5 Adverse Event Follow-Up

Subjects who present with unresolved or new AEs at the final visit or early termination will be followed by the Investigator until the AE has stabilized.

Resolution of an AE occurs when the subject has returned to his/her baseline state of health. Stabilization occurs when the Investigator does not expect further improvement or worsening of the AE. The PI will continue to report any follow-up information considered CS to the Sponsor.

8.6 Pregnancy

Pregnant females will not be enrolled in the study. Any pregnancy that occurs between the initial Screening Visit and check-in of Test Visit 1 will exclude that subject from study participation. If a pregnancy occurs after enrollment, the subject will be dismissed from the study. The pregnancy will be documented as an update to the subject's medical history, but will not be reported as an AE. The female subject will be referred to her primary care physician for proper obstetrical follow-up.

9. CONCOMITANT MEDICATIONS

From the time of providing informed consent through study completion (or early termination), subjects will not be permitted to use any other tobacco- or nicotine-containing products other than UB cigarettes or study STPs.

Concomitant medications that would exclude a subject from study participation include:

- All nicotine replacement products
- Varenicline (Chantix)
- Bupropion (Wellbutrin, Zyban)
- Lobelia extract
- In female subjects ≥ 35 years of age, use of systemic, estrogen-containing contraception or hormone replacement therapy
- Anticoagulants including but not limited to:
 - Clopidogrel (Plavix[®])
 - Warfarin (Coumadin[®], Jantoven[®])
 - Aspirin (> 325 mg/day)

Concomitant medications to treat chronic health conditions will be permitted during study participation provided that the medications are not exclusionary and that doses are stable (as determined by the Investigator).

All medications (including over-the-counter, vitamin/mineral supplements, other dietary supplements and herbal supplements) taken by subjects from up to 30 days prior to the Screening Visit through study completion (or early termination) will be documented on source documents using a Lexi-Comp medication database.

Prior and concomitant medications will be coded using the World Health Organization (WHO) Drug Dictionary.

10. QUALITY CONTROL AND ASSURANCE

This study will be performed and reported in compliance with the protocol, applicable standard operating procedures (SOPs), and applicable regulations and guidelines.

Prior to study commencement, a site initiation visit will be held to train the Investigators and study coordinators on the protocol, source document completion, safety, study product handling, ECO measurement, and questionnaires, and to review Good Clinical Practices (GCPs).

Source documents, in paper and electronic form, will be designed to allow capture and recording of all protocol-required information for each subject. Completed source documents will be reviewed and signed by the PI (or designee) to confirm accuracy and completeness.

Monitoring and auditing procedures will be followed, in order to comply with GCP guidelines. Monitoring of the source documents for completeness and clarity and verifying status of regulatory documents will be performed.

Regulatory authorities, the IRB, and/or RJRT's designee may request access to all source documents, and other study documentation for on-site audit or inspection. Direct access to these documents must be guaranteed by the Investigator, who must provide support at all times for these activities.

11. PLANNED STATISTICAL METHODS

11.1 General Considerations

Statistical significance is specified at p-values of 0.05 or less. No interim analyses are planned. All available data collected per protocol will be included in the analyses. Data collected under protocol deviation will be included at the Sponsor's discretion. Since this study is of an investigative nature, additional and/or alternate analyses may be performed as deemed appropriate. Calculations will be performed using SAS[®] Version 9.1 or higher.

Summaries and/or analyses will be defined in the Statistical Analysis Plan (SAP).

11.2 Determination of Sample Size

Based on the requirements of the randomization method (i.e., Williams Design), the target number for completion of this study is a minimum of 16 subjects.

11.3 Analysis of Nicotine Uptake

(b) (4)



11.4 Analysis of Tobacco Abstinence Symptoms

Descriptive statistics will be provided for each of the nicotine craving/tobacco abstinence questionnaire responses. Paired t-tests will be used to assess changes in nicotine craving/tobacco abstinence ratings between pre-product use and each time post-product use for each of the products.

11.5 Safety Analysis

Safety data will be summarized by study product and assessed using standard approaches that will be defined in the SAP.

12. ADMINISTRATIVE CONSIDERATIONS

12.1 Institutional Review Board

In accordance with 21 Code of Federal Regulation (CFR) 56, IRB approval is required for the protocol, ICF, subject recruitment materials, and for any other written information provided to subjects. The Investigator is responsible for submitting all said documents to the IRB for review and approval. Approval of the protocol and ICF is required prior to study commencement. The Investigator must also submit any other information that the IRB may request for review and approval. The Investigator will maintain all IRB-approved documents in the study file. Copies of the IRB response/approval and all other IRB-approved documents will be provided to the Sponsor.

The IRB will be provided with progress reports at appropriate intervals (not to exceed one year) and a Study Progress Report following the completion, termination, or discontinuation of the Investigator's participation in the study.

12.2 Ethical Conduct of the Study

This clinical study will be conducted in accordance with the US CFRs governing Protection of Human Subjects (21 CFR 50), Financial Disclosure by Clinical Investigator (21 CFR 54) and IRBs (21 CFR 56). In addition to the federal regulations, this study will follow the guidelines of the International Conference on Harmonization (ICH), commonly known as GCPs, which are consistent with the Declaration of Helsinki.

12.3 Subject Informed Consent

Prior to undergoing any study-related procedures, subjects must voluntarily consent to participate in the study by signing and dating the IRB-approved ICF. All procedures and risks must be explained to all subjects in a form understandable to them. Each subject must be given the opportunity to ask questions. Subjects will be informed that participation is voluntary and that they can withdraw from the study at any time for any reason.

The ICF will contain all elements required by ICH guidelines for GCP and any additional elements required by local regulations.

A copy of the signed ICF will be provided to the subject. The original signed ICF will be maintained with the subject's records.

12.4 Subject Confidentiality

In order to maintain subject privacy, all source documents, study reports, and communications will identify the subject by initials and the assigned subject number. The Investigator will grant monitor(s) and auditor(s) from RJRT or its designee and regulatory authority (ies) access to the subject's original study records for verification of data gathered on source documents and to audit the data collection process. The subject's confidentiality

will be maintained and will not be made publicly available to the extent permitted by applicable laws and regulations.

12.5 Study Monitoring

During the study, representatives of the Sponsor must be permitted to visit the study site location to assess compliance with the protocol and adherence to regulatory and GCP requirements. The study monitor will conduct scheduled on-site visits to review and verify source document completion. Storage and dispensing of study products, reporting of AEs, and maintenance and retention of study records will also be reviewed. The study monitor will adhere to all requirements for subject confidentiality as outlined in the ICF. The Investigator and staff will be expected to cooperate with the study monitor and to be available during a portion of the monitoring visits to answer questions.

12.6 Source Documents and Study Records

The Investigator must generate and maintain adequate and accurate records to enable full documentation of study conduct. Study data will primarily be recorded on an electronic source document system. Paper source documents may include, but are not limited to, the ICF and questionnaires. Collection of data on paper source will be noted as such in the electronic source document system. The Investigator must retain all original source documents in conjunction with the study site.

Source documents will be completed by the study site staff at the time study procedures are completed and must be completed for each subject. All data required by the protocol must be reported accurately on the source documents. The PI (or designee) will review and sign completed source documents.

12.7 Records Retention

All source documents, records, and reports will be retained by the study site for a minimum period of 5 years after the last subject exits the study, or as otherwise specified by the Sponsor.

All primary data, or copies thereof (e.g., questionnaires, ICFs, correspondence, photocopies, other source documents) that are a result of the original observations and activities of the study and are necessary for the reconstruction and evaluation of any study report will be maintained in the study site archives.

12.8 Publication and Disclosure Policy

All study-related information provided to the site as well as all information collected and documented during the course of the study will be regarded as confidential. The Investigator and clinical staff agree not to disclose such information in any way (e.g., publication or presentation) without prior written permission from the Sponsor.

13. REFERENCE LIST

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APPENDICES

Appendix 1: Fagerström Test for Nicotine Dependence

1. How soon after you wake up do you smoke your first cigarette?

Within 5 minutes _____ (3)
6 - 30 minutes _____ (2)
31- 60 minutes _____ (1)
After 60 minutes _____ (0)

2. Do you find it difficult to refrain from smoking in places where it is forbidden e.g. in church, at the library, in cinema, etc.?

Yes _____ (1)
No _____ (0)

3. Which cigarette would you hate most to give up?

The first one in the morning _____ (1)
Any other.. _____ (0)

4. How many cigarettes per day do you smoke?

≤ 10. _____ (0)
11-20 _____ (1)
21-30 _____ (2)
≥ 31. _____ (3)

5. Do you smoke more frequently during the first hours after waking than during the rest of the day?

Yes _____ (1)
No _____ (0)

6. Do you smoke if you are so ill that you are in bed most of the day?

Yes _____ (1)
No _____ (0)

Reproduced with permission.

Source: Heatherton TF, *et al.* 1991. The Fagerström Test for Nicotine Dependence: a revision of the Fagerström Tolerance Questionnaire. *Br J Addict* 86(9):1119-27.

Appendix 2: Mood and Physical Symptoms Scale

Please show for each of the items below how you currently feel.
(Circle one number for each item.)

	Not at all	Slightly	Somewhat	Very	Extremely
1. Depressed	1	2	3	4 5	
2. Anxious	1	2	3	4 5	
3. Irritable	1	2	3	4 5	
4. Restless	1	2	3	4 5	
5. Hungry	1	2	3	4 5	
6. Poor concentration	1	2	3	4 5	

7. How strong is your current urge to smoke? (Circle one number.)

No urges	Slight	Moderate	Strong	Very strong	Extremely strong
0	1 2 3 4 5				

Reproduced with permission.

Source: West R, Hajek P. 2004. Evaluation of the mood and physical symptoms scale (MPSS) to assess cigarette withdrawal. Psychopharmacology. 177:195-199.

Appendix 3: Exit Questionnaire

Your opinion counts! Please give us your input about the study you are completing. Answer each question by circling the number corresponding to the best answer. Circle only one choice unless indicated otherwise. When completed, please return your questionnaire to a study staff member.

- 1) Below is a list of activities that were required of you during the course of the study. On a scale of 1 to 7, with 1 being “Extremely Unappealing,” 4 being neither “Neither Appealing nor Unappealing” and 7 being “Extremely Appealing,” how appealing was each of the following activities to you? (Circle one rating for each item.)

	(Circle one rating for each)						
	Extremely Unappealing			Neither Appealing nor Unappealing			Extremely Appealing
Visits every week	1	2	3	4 5		6	7
Travel to and from the site	1	2	3	4 5		6	7
Compensation	1	2	3	4 5		6	7
Length of the study	1	2	3	4 5		6	7
Products you were asked to use	1	2	3	4 5		6	7
Completing questionnaires	1	2	3	4 5		6	7
12-hour smoking abstinence	1	2	3	4 5		6	7
Catheter insertion	1	2	3	4 5		6	7
Blood collection	1	2	3	4 5		6	7
3-4 hour study visits	1	2	3	4 5		6	7

- 2) How would you rate each of the following characteristics of the study? (Circle one rating for each item.)

	(Circle one rating for each)				
	Poor	Fair	Good	Very Good	Excellent
Convenience of the site location	1	2	3 4		5
Cleanliness of the facilities	1	2	3 4		5
Comfort of the site	1	2	3 4		5
Comfort with the nurses	1	2	3 4		5
Comfort with other study team members	1	2	3 4		5
Encouragement and motivation by the study team members in helping me achieve my study goals	1	2	3	4	5

- 3) Why or why not would you consider participating in a similar study in the future?
(Please be as specific as possible.)

- 4) Did you enjoy participating in this study? Why or why not? (Please be as specific as possible.)

- 5) Do you have any additional comments or suggestions that you would like to share with us? (Please be as specific as possible.)

PRINCIPAL INVESTIGATOR'S SIGNATURE

Study Title: Assessment of Smokers' Nicotine Uptake and Urge to Smoke After Use of Smokeless Tobacco Products

Protocol Number: CSD1101

I have carefully read and understand the protocol described above. I agree to comply with all applicable regulations and the conduct and terms of the study specified therein.

Signed: _____

Gregory P. Tarleton, PharmD, MD
Bellomy Research
4305 Enterprise Drive, Suite E
Winston-Salem, North Carolina 27106

Date: 7/22/11



**INDEPENDENT
INVESTIGATIONAL
REVIEW BOARD INC.**

Your Advocate for Clinical Research Participants



DATE: August 26, 2011

TO: Gregory P. Tarleton, Pharm D, MD
Principal Investigator

FROM: Authorized Signatory 
Independent Investigational Review Board, Inc.

SUBJECT: Administrative Letter dated 24-Aug-2011;

PROTOCOL: CSD1101

The Independent Investigational Review Board, Inc. had an opportunity to review the above referenced Administrative Letter for the above noted research study. The Administrative Letter identified that mean platelet volumes will not be documented for this study. It was noted that the Principal Investigator has confirmed that there are no subject safety concerns due to this change. This submission met the criteria for a minor change in previously approved research and was reviewed under expedited review procedures on 26-Aug-2011.

The Administrative Letter is approved. The Administrative Letter does not require a change to the consent form.

Thank you for your cooperation.

FC/JB/mb:dg:



R.J. Reynolds Tobacco Company

Mitchell F. Stiles, MBA
Senior Manager, Product Integrity
Research and Development

Phone: 336-741-2651

Fax: 336-741-2841

stilesm@rjt.com

August 24, 2011

Frances Conway, RN, CIP, Chair
Independent Investigational Review Board, Inc.
6738 W. Sunrise Blvd., Suite 102
Plantation, Florida 33313

RE: RJRT Protocol CSD1101 – Assessment of Smokers' Nicotine Uptake and Urge to Smoke After Use of Smokeless Tobacco Products (Version 1.0, 22 July 2011)

Dear Frances:

This letter is intended to notify you of a minor change to protocol Version 1.0 with regard to Clinical Laboratory Tests. Section 7.1.3 of Version 1.0 states that mean platelet volume will be included as part of the complete blood count (CBC) results. The central laboratory that will perform all clinical laboratory testing does not and will not report results for mean platelet volume. The Principal Investigator has confirmed that there are no subject safety concerns related to not obtaining and/or documenting mean platelet volume results. Therefore, mean platelet volume will not be documented for recruited and/or enrolled study subjects for RJRT CSD1101.

Please feel free to contact me with any questions. Thank you for your assistance in this matter.

Kind regards,

A handwritten signature in black ink that reads "Mitchell F. Stiles".

Mitchell F. Stiles, MBA

cc: Gregory P. Tarleton, MD, PharmD

16.1.2 Sample Electronic Source Forms

Sample data collection forms are provided on the following pages.

☐ I have verified that this is the correct chart.

Visit Information

Visit Date / / 

Informed Consent

☐ Yes ☐ No Has the subject signed Informed Consent?


☐ Yes ☐ No Was the subject given adequate time to read Informed Consent and to have his/her questions addressed prior to signing the form?

☐ Yes ☐ No Informed Consent discussion was conducted by:

☐ Yes ☐ No Informed Consent version date:

/ /

was voluntarily signed by subject on:

/ / 

at : :

☐ Yes ☐ No A signed copy of Informed Consent was given to the subject for his/her record.

☐ Yes ☐ No Subject's age was verified by an acceptable form of ID.

☐ Yes ☐ No Copy of subject's ID was made.

By entering my username and password I am affixing my electronic signature to this form. I state that I have reviewed the Informed Consent form with the subject and answered any questions that the subject had.

Investigator's Signature

Contraception Method

☐ Yes ☐ No ☐ NA, Male Will contraception information be documented?

☐ Yes ☐ No Has the subject given birth within the past 12 months or is the subject currently breast feeding?

Subject's reproductive status:

- ☐ Using acceptable form of contraception
- ☐ Surgically sterile for at least 90 days:
- ☐ tubal ligation ☐ ovariectomy
- ☐ hysterectomy ☐ other, specify below

Method of contraception:

- ☐ oral BC ☐ IUD ☐ implantable contraceptives
- ☐ barrier method ☐ injectible contraceptive

☐ Yes ☐ No Subject agrees to use acceptable contraception method from the time of signing the informed consent through study

Comments:

Usual Brand Cigarette Pack

☐ Yes ☐ No Usual brand cigarette pack information section was intentionally left blank.

☐ Yes ☐ No Photocopy of subject's usual brand of cigarettes was made for study records.

Usual brand name: _____

Length:

- ☐ 72 mm
☐ 83 mm
☐ 85 mm
☐ 99 mm
☐ 100 mm
☒ 120 mm

Packaging:

- ☐ soft pack
☐ hard pack

Filter type:

- ☐ standard
☐ non-filter

Type:

- ☐ menthol
☐ non-menthol

UB with length of 72 mm, 120 mm, and non-filter cigarettes are excluded from study.

Number of cigarettes the subject typically smokes per day:

Number of cigarettes typically smoked per day is outside protocol specified range of 10-30.

Length of time subject has smoked: years

Estimated number of cigarettes smoked today:

Comments: _____

Vital Signs

☐ Yes ☐ No Vital signs section was intentionally left blank.

Vital signs were collected on / /



TIME
SEATED

TIME
MEASURED
(after seating for 5 min)

SEATED
BLOOD PRESSURE
mm/Hg

SELECTED
READING

Collection time is < 5 minutes from the time seated.

: : / ☐ 1st

BP is outside protocol specified range of < or equal to 200/100 mm/Hg.

Collection time is < 5 minutes from the time seated.

: : / ☐ 2nd

BP is outside protocol specified range of < or equal to 200/100 mm/Hg.

Collection time is < 5 minutes from the time seated.

: : / ☐ 3rd

BP is outside protocol specified range of < or equal to 200/100 mm/Hg.

Collection time is < 5 minutes from the time seated.

: : / ☐ 4th

BP is outside protocol specified range of < or equal to 200/100 mm/Hg.

TIME SEATED

TIME MEASURED
(after seating for 5 min)

HEART RATE

: :

Collection time is < 5 minutes from the time seated.

Oral temperature . ☒ F° ☐ C° 37.1 Degrees C


Expired Carbon Monoxide

☐ Yes ☐ No ECO section was intentionally left blank.

Last cigarette extinguished by subject was

on / / at :

(Time is approximate/estimated based on subjects self-report).

ECO was performed on / / 

SMOKERLYZER ID

TIME MEASURED

ECO

SELECTED
READING

11 : 45 012 ☐ 1st

ECO reading is outside protocol defined range of 15-100 ppm.

Baseline ECO reading should be performed between 12 and 6 pm.

: 012 ☐ 2nd

ECO reading is outside protocol defined range of 15-100 ppm.

: 012 ☐ 3rd

ECO reading is outside protocol defined range of 15-100 ppm.

: 012 ☐ 4th

ECO reading is outside protocol defined range of 15-100 ppm.

Physical and Oral Examination

☐ Yes ☐ No Physical and oral examination section was intentionally left blank.

Weight: . lbs Height: . in

Subjects weight is less than 110 lbs which is an exclusion from the study.

Physical and Oral Examination cont.

SITE/SYSTEM	If Abn, specify CS or NCS and record symptoms/diagnosis	
Heart	<input type="checkbox"/> nl <input type="checkbox"/> abn <input type="checkbox"/> nd	<input type="checkbox"/> CS _____ <input type="checkbox"/> NCS _____
		<input type="checkbox"/> CS _____ <input type="checkbox"/> NCS _____
Lungs	<input type="checkbox"/> nl <input type="checkbox"/> abn <input type="checkbox"/> nd	<input type="checkbox"/> CS _____ <input type="checkbox"/> NCS _____
		<input type="checkbox"/> CS _____ <input type="checkbox"/> NCS _____
Abdomen	<input type="checkbox"/> nl <input type="checkbox"/> abn <input type="checkbox"/> nd	<input type="checkbox"/> CS _____ <input type="checkbox"/> NCS _____
		<input type="checkbox"/> CS _____ <input type="checkbox"/> NCS _____
Skin	<input type="checkbox"/> nl <input type="checkbox"/> abn <input type="checkbox"/> nd	<input type="checkbox"/> CS _____ <input type="checkbox"/> NCS _____
		<input type="checkbox"/> CS _____ <input type="checkbox"/> NCS _____
Ears/Nose/ Throat (ENT)	<input type="checkbox"/> nl <input type="checkbox"/> abn <input type="checkbox"/> nd	<input type="checkbox"/> CS _____ <input type="checkbox"/> NCS _____
		<input type="checkbox"/> CS _____ <input type="checkbox"/> NCS _____

Physical and Oral Examination cont.

SITE/SYSTEM	If Abn, specify CS or NCS and record symptoms/diagnosis	
Neck	<input type="checkbox"/> nl	<input type="checkbox"/> CS _____
	<input type="checkbox"/> abn	<input type="checkbox"/> ncs _____
	<input type="checkbox"/> nd	
		<input type="checkbox"/> CS _____
		<input type="checkbox"/> ncs _____
Evidence of leukoplakia	<input type="checkbox"/> yes	<input type="checkbox"/> CS _____
	<input type="checkbox"/> no	<input type="checkbox"/> ncs _____
	<input type="checkbox"/> nd	
Evidence of other oral keratosis	<input type="checkbox"/> yes	<input type="checkbox"/> CS _____
	<input type="checkbox"/> no	<input type="checkbox"/> ncs _____
	<input type="checkbox"/> nd	
Evidence of oral lesions	<input type="checkbox"/> yes	<input type="checkbox"/> CS _____
	<input type="checkbox"/> no	<input type="checkbox"/> ncs _____
	<input type="checkbox"/> nd	

Comments: _____


By entering my username and password I am affixing my electronic signature to this form. I state that I have conducted a complete physical examination (per the protocol) of this subject and have identified and noted, to the best of my ability, any significant abnormalities that may preclude this subject from safely continuing in the trial.

Physician Signature

Clinical Laboratory Samples Collection

☐ Yes ☐ No Clinical laboratory sample collection section was intentionally left blank.

Blood samples were collected: ☐ Yes ☐ No


on / / at : 

by

for: Comprehensive metabolic profile (CMP) ☐ Yes ☐ No
including triglycerides and total cholesterol.

Complete blood count (CBC) ☐ Yes ☐ No

Urine sample was collected ☐ Yes ☐ No

on / / at : 

by

for: Urinalysis (macroscopic) ☐ Yes ☐ No

Urine drug test ☐ Yes ☐ No

Urine pregnancy test ☐ Yes ☐ No ☐ NA, Male

Comments: _____

Clinical Laboratory Samples Collection cont.

Drug test was performed by

Drug Screen test results: ☒ Positive ☐ Negative

Positive urine drug screen may exclude subject from study.
Verify and/or update concomitant medications.

Investigator notes for positive drug test result:

Pregnancy test was performed by

Pregnancy test results: ☒ Positive ☐ Negative

Positive pregnancy test excludes subject from study.

Investigator notes for positive pregnancy test result:

Reminders

☐ Yes ☐ No Reminders section was intentionally left blank.

☐ Yes ☐ No ☐ NA MPSS and Fagerstrom questionnaires were completed by subject.

☐ Yes ☐ No ☐ NA Subject was provided with Cigarette Use Log for recording daily cigarette use.

☐ Yes ☐ No ☐ NA Reminder Study Calendar was given to the subject.


☐ Yes ☐ No Study Contact Card was given to the subject.

☐ Yes ☐ No Subject was instructed to abstain from all tobacco and nicotine use for at least 12 hours prior to each Test Visit.

☐ Yes ☐ No Subject was instructed not to smoke or otherwise consume any tobacco or nicotine-containing product other than their UB cigarettes until study completion.

☐ I have verified that this is the correct chart.

Visit Information

Visit Date / / 

The Fagerstrom Test

☐ Yes ☐ No The Fagerstrom Test for Nicotine Dependence section was intentionally left blank.

The Fagerstrom Test for Nicotine Dependence was completed by subject on:

/ / at: :

☐ Yes ☐ No FTND questionnaire data was transcribed from paper questionnaire form completed by the subject.

1. How soon after you wake up do you smoke your first cigarette?

- ☐ Within 5 minutes ☐ 31-60 minutes
☐ 6-30 minutes ☐ After 60 minutes

2. Do you find it difficult to refrain from smoking in places where it is forbidden e.g. in church, at the library, in cinema, etc.?

☐ Yes ☐ No

3. Which cigarette would you hate most to give up?

- ☐ The first one in the morning
☐ Any other

4. How many cigarettes per day do you smoke?

- ☐ < or = 10
☐ 11-20
☐ 21-30
☐ > or = 31

5. Do you smoke more frequently during the first hours after waking than during the rest of the day?

☐ Yes ☐ No

6. Do you smoke if you are so ill that you are in bed most of the day?

☐ Yes ☐ No

Mood and Physical Symptoms Scale

☐ Yes ☐ No Mood and Physical Symptoms Scale (MPSS) section was intentionally left blank.

MPSS was completed by subject on:

/

/

at:

:

☐ Yes ☐ No MPSS questionnaire data was transcribed from paper questionnaire form completed by the subject.

	Not at all	Slightly	Somewhat	Very	Extremely
1. Depressed	(1)	(2)	(3)	(4)	(5)
2. Anxious	(1)	(2)	(3)	(4)	(5)
3. Irritable	(1)	(2)	(3)	(4)	(5)
4. Restless	(1)	(2)	(3)	(4)	(5)
5. Hungry	(1)	(2)	(3)	(4)	(5)
6. Poor concentration	(1)	(2)	(3)	(4)	(5)

7. How strong is your current urge to smoke? (Check one number)

No urges	Slight	Moderate	Strong	Very strong	Extremely strong
(0)	(1)	(2)	(3)	(4)	(5)

☐ I have verified that this is the correct chart.

Visit Information

Visit date must be on or before the current date.

Visit Date

10 / Sep / 2012



Comprehensive Metabolic Profile (CMP)

☐ Yes ☐ No Comprehensive metabolic (CMP) test results data captured.

CMP test accession number:

was

reported by Solstas Lab Partners on

/

/

TEST NAME	RESULT	RATING
Sodium	<div></div> mEq/L	<input type="checkbox"/> cs <input type="checkbox"/> ncs
Potassium	<div></div> mEq/L	<input type="checkbox"/> cs <input type="checkbox"/> ncs
Chloride	<div></div> mEq/L	<input type="checkbox"/> cs <input type="checkbox"/> ncs
Chloride value meets alert value level of < 65 mEq/L or > 130 mEq/L.		
Carbon Dioxide (CO2)	<div></div> mEq/L	<input type="checkbox"/> cs <input type="checkbox"/> ncs
CO2 value meets alert value level of < 10 mEq/L or > 40 mEq/L.		
Glucose	<div></div> mg/dL	<input type="checkbox"/> cs <input type="checkbox"/> ncs
BUN	<div></div> mg/dL	<input type="checkbox"/> cs <input type="checkbox"/> ncs

TEST NAME	RESULT	RATING
Creatinine	<input checked="" type="checkbox"/> Male <input type="checkbox"/> Female <div> <div></div><div>1</div><div>1</div> </div> . <div> <div>1</div><div>1</div> </div> mg/dL	<input type="checkbox"/> cs <input type="checkbox"/> ncs
Creatinine value is outside protocol allowable range of < or = 1.6 mg/dL.		
Bilirubin, Total	<div> <div></div><div></div> </div> . <div> <div></div> </div> mg/dL	<input type="checkbox"/> cs <input type="checkbox"/> ncs
Alkaline Phosphatase	<div> <div></div><div></div><div></div><div></div> </div> U/L	<input type="checkbox"/> cs <input type="checkbox"/> ncs
AST/SGOT	<div> <div>5</div><div>5</div><div>5</div> </div> U/L	<input type="checkbox"/> cs <input type="checkbox"/> ncs
AST/SGOT is outside protocol allowable range at Screening of > 2 x ULN.		
ALT/SGPT	<input checked="" type="checkbox"/> Male <input type="checkbox"/> Female <div> <div>2</div><div>0</div><div>8</div> </div> U/L	<input type="checkbox"/> cs <input type="checkbox"/> ncs
ALT/SGPT is outside protocol allowable range at Screening of > 2 x ULN.		
Total Protein	<div> <div></div><div></div> </div> . <div> <div></div> </div> g/dL	<input type="checkbox"/> cs <input type="checkbox"/> ncs
Albumin	<div> <div></div><div>0</div> </div> . <div> <div>1</div> </div> g/dL	<input type="checkbox"/> cs <input type="checkbox"/> ncs
Albumin value meets alert value level of less than 2.0 g/dL.		
Calcium	<div> <div></div><div></div><div>0</div> </div> . <div> <div>1</div> </div> mg/dL	<input type="checkbox"/> cs <input type="checkbox"/> ncs
Calcium value meets critical value level of < 6.5 mg/dL or > 13.0 mg/dL.		
Cholesterol	<div> <div></div><div></div><div></div><div></div> </div> mg/dL	<input type="checkbox"/> cs <input type="checkbox"/> ncs
Triglyceride	<div> <div></div><div></div><div></div><div></div> </div> mg/dL	<input type="checkbox"/> cs <input type="checkbox"/> ncs

Complete Blood Count (CBC)

☐ Yes ☐ No Complete blood count (CBC) test results data captured.

CBC test accession number was

reported by Solstas Lab Partners on / /

TEST NAME	RESULT	RATING
WBC	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> K/uL	<input type="checkbox"/> cs <input type="checkbox"/> ncs
RBC	<input type="checkbox"/> Male <input type="text"/> <input type="text"/> <input type="checkbox"/> Female <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/> MIL/uL	<input type="checkbox"/> cs <input type="checkbox"/> ncs
Hemoglobin	<input checked="" type="checkbox"/> Male <input type="text"/> <input type="text"/> 0 . <input type="text"/> 1 g/dL <input type="checkbox"/> Female	<input type="checkbox"/> cs <input type="checkbox"/> ncs
Hemoglobin value is outside the protocol allowable range of > or = 12.5 g/dL.		
Hematocrit	<input checked="" type="checkbox"/> Male <input type="text"/> <input type="text"/> 0 . <input type="text"/> 1 % <input type="checkbox"/> Female	<input type="checkbox"/> cs <input type="checkbox"/> ncs
Hematocrit value meets critical value level of < 15 % or > 65 %.		
MCV	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> fL	<input type="checkbox"/> cs <input type="checkbox"/> ncs
MCH	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> g/dL	<input type="checkbox"/> cs <input type="checkbox"/> ncs
MCHC	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> g/dL	<input type="checkbox"/> cs <input type="checkbox"/> ncs
RDW	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> %	<input type="checkbox"/> cs <input type="checkbox"/> ncs

TEST NAME	RESULT	RATING
Platelet (PLT)	<div> <div></div> <div></div> <div></div> <div>1</div> </div> K/uL	<input type="checkbox"/> cs <input type="checkbox"/> ncs
Platelet value meets critical value level of < 30 K/uL or > 1500 K/uL.		

Urinalysis (Macroscopic)

☐ Yes ☐ No Urinalysis (macroscopic) test results data captured.

Urinalysis test accession number was
reported by Solstas Lab Partners on / /

TEST NAME	RESULT	RATING
Color	colorless	<input type="checkbox"/> cs <input type="checkbox"/> ncs
Appearance	slightly cloudy	<input type="checkbox"/> cs <input type="checkbox"/> ncs
Specific Gravity	<div><div></div></div> . <div><div></div><div></div><div></div></div>	NA
pH	<div><div></div></div> . <div><div></div></div>	NA
Glucose	<div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div></div> mg/dL	<input type="checkbox"/> cs <input type="checkbox"/> ncs
Bilirubin	small (+)	<input type="checkbox"/> cs <input type="checkbox"/> ncs
Ketone	trace (5) mg/dL	<input type="checkbox"/> cs <input type="checkbox"/> ncs
Blood	negative	<input type="checkbox"/> cs <input type="checkbox"/> ncs
Protein	trace mg/dL	<input type="checkbox"/> cs <input type="checkbox"/> ncs

TEST NAME	RESULT	RATING
Urobilinogen	<input type="text"/> . <input type="text"/> mg/dL	<input type="checkbox"/> cs <input type="checkbox"/> ncs
Nitrite	positive	<input type="checkbox"/> cs <input type="checkbox"/> ncs
Leukocytes	small (1+)	<input type="checkbox"/> cs <input type="checkbox"/> ncs

Clinical Laboratory Test Review

☐ Yes ☐ No

All of the clinical laboratory test results were reviewed by Investigator and the subject meets all of the eligible laboratory criteria for the study.

By entering my username and password I am affixing my electronic signature to this form. I state that I have conducted a complete review of laboratory test results (per the protocol) for this subject and have identified and noted, to the best of my ability, any significant abnormalities that may preclude this subject from safely participating in the trial based on careful review of eligibility criteria.

Investigator Signature

Next Visit Information

☐ Yes ☐ No Was the subject contacted?

Subject was talked to directly on / /

and was informed that he/she:

- ☐ qualifies to return for Test Visit
☐ does not qualify for study participation

☐ Yes ☐ No Test Visit 1 was scheduled with subject on

/ / at :

Comments: _____

☐ I have verified that this is the correct chart.

Inclusion Criteria

Patient may not continue in the study without a sponsor waiver.

Inclsuion Criteria	Yes	No	ND
1. Able to comprehend and willing to sign an informed consent form (ICF).	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. Able to read, comprehend, and complete questionnaires in English.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Male or female, age 21-55 years, inclusive.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Generally healthy based on screening assessments, as judged by the PI.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Primary tobacco use is smoking cigarettes.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Smokes combustible, filtered cigarettes, 83 mm or 100 mm length, menthol or non-menthol.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Self-reported daily use of 10 to 30 cigarettes at Screening Visit.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Willing to abstain from tobacco and nicotine use for at least 12 hours prior to each study product administration.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Females must be willing to use a form of contraception acceptable to the Investigator from the time of signing consent until discharge or be surgically sterile for at least 90 days prior to enrollment. <input type="checkbox"/> NA	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Exclusion Criteria

Patient may not continue in the study without a sponsor waiver.

Exclusion Criteria	Yes	No	ND
1. Postponing a decision to quit smoking (defined as planning a quit attempt within a month of the Screening Visit) to participate in the study.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Employed by a tobacco company, a sub-contractor of a tobacco-company, or handles tobacco as part of their job.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Current oral lesion(s) at the Screening Visit.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. A history of clinically significant (CS) heart disease, kidney disease, asthma or any other lung disease, diabetes, liver disease, neurological disease, or psychiatric disorder, as determined by the Investigator.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Self-reports human immunodeficiency virus (HIV), Hepatitis B, or Hepatitis C infection.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Current diagnosis of peptic ulcers or irritable bowel syndrome at the Screening Visit.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Uncontrolled hypertension defined as a systolic blood pressure of ≥ 200 mmHg or a diastolic blood pressure of ≥ 100 mmHg.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Hemophilia or any other bleeding disorders.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Clotting disorders with concomitant use of anticoagulants (see Section 9 "Concomitant Medications").	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Given a whole blood donation within 8 weeks (56 days) prior to the Screening Visit.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Weights < 110 pounds.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Poor peripheral venous access (at Screening or Test Visit 1).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Exclusion Criteria

Patient may not continue in the study without a sponsor waiver.

Exclusion Criteria	Yes	No	ND
13. Hemoglobin level is < 12.5 g/dL at the Screening Visit.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Elevated liver function test (LFT) results > 2 times the upper limits of normal on the clinical laboratory tests obtained at the Screening Visit.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Serum creatinine level > 1.6 mg/dL on the clinical laboratory tests obtained at the Screening Visit.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. Any laboratory value (on clinical laboratory tests obtained at the Screening Visit) outside the laboratory reference range, considered by the PI to be clinically significant (CS).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. ECO level is < 15 parts per million (ppm) or > 100 ppm at the Screening Visit, measured between 12 p.m. and 6 p.m.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. ECO level is > 12 ppm at check-in of the Test Visit 1.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. Use of cigars or electronic cigarette devices within 30 days prior to the Screening Visit.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. Use of any type of smokeless tobacco or non-tobacco nicotine-containing product(s) within 30 days of the Screening Visit.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21. Use of illegal substances within 30 days of the Screening Visit.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. Use of any medication or supplement that aids smoking cessation, including varenicline (Chantix®) and bupropion (Wellbutrin®, Zyban®), within 30 days of the Screening Visit.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23. Use of lobelia extract within 30 days of the Screening Visit.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24. Self-reports a history of illegal intravenous (IV) drug use.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Exclusion Criteria

Patient may not continue in the study without a sponsor waiver.

Exclusion Criteria	Yes	No	ND
25. Self-reports drinking more than 14 servings of alcoholic beverages per week (1 serving = 12 oz of beer, 6 oz of wine, or 1 oz of liquor).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26. A positive urine drug screen without disclosure of corresponding prescribed concomitant medication(s), at the Screening Visit or check-in at Test Visit 1.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27. Females with a positive urine pregnancy test. <input type="checkbox"/> NA	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
28. Females that have given birth within the past 12 months prior to the Screening Visit or are currently breastfeeding. <input type="checkbox"/> NA	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
29. Females \geq 35 years of age currently using systemic, estrogen-containing contraception or hormone replacement therapy. <input type="checkbox"/> NA	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30. Deemed by the PI to be unsuitable for the study due to a medical condition, disease, concomitant medication or any other reason not previously listed that in the opinion of the PI would make the subject unsuitable in this clinical trial.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Eligibility Criteria Review

Subject did not meet eligibility criteria: Exclusion criteria #21

Explanation: _____

Exemption granted? ☐ Yes ☐ No

Exemption granted on: / /

Eligibility Criteria Review

Subject did not meet eligibility criteria: Inclusion criteria #1

Explanation:

Exemption granted? ☐ Yes ☐ No

Exemption granted on:

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Subject did not meet eligibility criteria: Inclusion criteria #1

Explanation:

Exemption granted? ☐ Yes ☐ No

Exemption granted on:

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Subject did not meet eligibility criteria: Exclusion criteria #21

Explanation:

Exemption granted? ☐ Yes ☐ No

Exemption granted on:

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Subject has been enrolled into the Study.

☐ Yes ☐ No. Subject has been dismissed or discharged.

Comments: _____

By entering my username and password I am affixing my electronic signature to this form. I state that I have reviewed all the Inclusion and Exclusion Criteria for this subject.

Investigator Signature

☐ I have verified that this is the correct chart.

Visit Information

Visit Date / / 

☐ Yes ☐ No Subject's ID/age was verified by an acceptable form of ID.

☐ Yes ☐ No Did the subject smoke any cigarettes other than his/her UB since last visit?

☐ Yes ☐ No Did the subject use any nicotine replacement products since last visit?

☒ Yes ☐ No Did subject use any tobacco products, other than cigarettes, since last visit?

Subject should be dismissed from study.

Comments:

Adverse Events

☒ Yes ☐ No Has the subject experienced any changes in health or any changes in existing conditions since the last visit?

Please update the Adverse Event or Medical History Log.

Concomitant Medications

☒ Yes ☐ No Have there been any changes in the subject's concomitant medications since last visit?

Please update the Concomitant Medication Log.

Informed Consent

☐ Yes ☐ No Is a new version of the Informed Consent available?


☐ Yes ☐ No Was the subject given adequate time to read Informed Consent and to have his/her questions addressed prior to signing the form?

☐ Yes ☐ No Informed Consent discussion was conducted by:

☐ Yes ☐ No Informed Consent version date

/ / version number .

was voluntarily signed by subject on

/ / 

at : :

prior to any further study procedure being performed.

☐ Yes ☐ No A signed copy of the Informed Consent was given to subject for his/her records.

Comments: _____

By entering my username and password I am affixing my electronic signature to this form. I state that I have reviewed the Informed Consent form with the subject and answered any questions that the subject had.

Investigator's Signature

Vital Signs

☐ Yes ☐ No Vital signs section was intentionally left blank.

Vital signs were collected on

/ /



TIME
SEATED

TIME
MEASURED
(after seating for 5 min)

SEATED
BLOOD PRESSURE
mm/Hg

SELECTED
READING

Collection time is < 5 minutes from the time seated.

13 : 36 13 : 36 / 101 ☐ 1st

BP is outside protocol specified range of < or equal to 200/100 mm/Hg.

Collection time is < 5 minutes from the time seated.

13 : 36 13 : 36 201 / ☐ 2nd

BP is outside protocol specified range of < or equal to 200/100 mm/Hg.

Collection time is < 5 minutes from the time seated.

13 : 36 13 : 36 / 101 ☐ 3rd

BP is outside protocol specified range of < or equal to 200/100 mm/Hg.

Collection time is < 5 minutes from the time seated.

13 : 36 13 : 36 201 / ☐ 4th

BP is outside protocol specified range of < or equal to 200/100 mm/Hg.

TIME SEATED

TIME MEASURED
(after seating for 5 min)

HEART RATE

13 : 36 13 : 36


Collection time is < 5 minutes from the time seated.

Oral temperature 98 . 8 ☒ F° ☐ C° 37.1 Degrees C

Urine Drug and Pregnancy Test

☐ Yes ☐ No Urine drug and pregnancy test section was intentionally left blank.

Urine sample was collected ☐ Yes ☐ No

on / / at : 

by

for: Urine drug test ☐ Yes ☐ No

Urine pregnancy test ☐ Yes ☐ No ☐ NA, Male

Drug test was performed by

Drug Screen test results: ☒ Positive ☐ Negative

Positive urine drug screen may exclude subject from study.
Verify and/or update concomitant medications.

Investigator notes for positive drug test result:

Pregnancy test was performed by

Pregnancy test results: ☒ Positive ☐ Negative

Positive pregnancy test excludes subject from study.

Investigator notes for positive pregnancy test result:

Comments: _____

Cigarette Use Log

☐ Yes ☐ No Cigarette Use Log section was intentionally left blank.

☐ Yes ☐ No Subject returned a completed Cigarette Use Log.

☐ Yes ☐ No Data from the log was transcribed in to the table below.

Day	Date	# of cigarettes smoked today
Day 1	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 2	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 3	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 4	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 5	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 6	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 7	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>

Last cigarette extinguished by subject was
on / / at :

Comments:

Cigarette Use Log cont. (Day 8-18)

Day	Date	# of cigarettes smoked today
Day 8	<div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 9	<div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 10	<div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 11	<div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 12	<div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 13	<div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 14	<div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 15	<div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 16	<div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 17	<div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 18	<div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>

Expired Carbon Monoxide

☐ Yes ☐ No ECO section was intentionally left blank.

ECO was performed on

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SMOKERLYZER ID	TIME MEASURED	ECO	SELECTED READING
<input type="text"/>	<input type="text"/> : <input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1st
ECO reading is outside protocol defined range of less or equal to 12 ppm.			
<input type="text"/>	<input type="text"/> : <input type="text"/>	<input type="text"/>	<input type="checkbox"/> 2nd
ECO reading is outside protocol defined range of less or equal to 12 ppm.			
<input type="text"/>	<input type="text"/> : <input type="text"/>	<input type="text"/>	<input type="checkbox"/> 3rd
ECO reading is outside protocol defined range of less or equal to 12 ppm.			
<input type="text"/>	<input type="text"/> : <input type="text"/>	<input type="text"/>	<input type="checkbox"/> 4th
ECO reading is outside protocol defined range of less or equal to 12 ppm.			



Eligibility Criteria Review


- ☐ Yes ☐ No Will the eligibility criteria form be reviewed and completed?
- ☐ Yes ☐ No Subject continues to meet all inclusion and exclusion criteria.
- ☐ Yes ☐ No Subject is enrolled in the study.


Comments:





In-Clinic Product and MPSS Administration












- ☐ Yes ☐ No In-clinic product and MPSS administration section was intentionally left blank.
- ☐ Yes ☐ No Pre-product administration MPSS was completed by subject prior to catheter insertion at : : 
- ☐ Yes ☐ No Subject provided 1 of their UB cigarettes for in-clinic use.
- ☐ Yes ☐ No UB descriptor information was confirmed.
- ☐ Yes ☐ No Subject was instructed to smoke the cigarette according to his/her typical pattern.

ACTION	COLLECTION WINDOW	TIME OF COLLECTION	COLLECTED IN WINDOW
Pre-0 Draw		<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> ND  NA
0' Draw	13:37:16 - 13:38:16	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> ND  <input type="checkbox"/> Yes <input type="checkbox"/> No

Product administration start time : : 

Product administration stop time : : 

ACTION	COLLECTION WINDOW	TIME OF COLLECTION	COLLECTED IN WINDOW
3' Draw	13:40:16 - 13:41:16	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
5' Draw	13:42:16 - 13:43:16	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
5' MPSS	13:42:46 - 13:43:46	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
7.5' Draw	13:44:46 - 13:45:46	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
10' Draw	13:47:16 - 13:48:16	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
15' Draw	13:52:16 - 13:53:16	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
15' MPSS	13:52:46 - 13:53:46	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
20' Draw	13:57:16 - 13:58:16	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
30' Draw	14:07:16 - 14:08:16	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
30' MPSS	14:07:46 - 14:08:46	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
45' Draw	14:22:16 - 14:23:16	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
45' MPSS	14:22:46 - 14:23:46	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No

ACTION	COLLECTION WINDOW	TIME OF COLLECTION	COLLECTED	IN WINDOW
60' Draw	14:37:16 - 14:38:16	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No
60' MPSS	14:37:46 - 14:39:46	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No
75' Draw	14:52:16 - 14:53:16	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No
90' Draw	15:07:16 - 15:08:16	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No
90' MPSS	15:07:46 - 15:09:46	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No
120' Draw	15:35:46 - 15:39:46	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No
120' MPSS	15:37:46 - 15:39:46	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No
150' Draw	16:05:46 - 16:09:46	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No
150' MPSS	16:07:46 - 16:12:46	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No
180' Draw	16:35:46 - 16:39:46	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No
180' MPSS	16:37:46 - 16:42:46	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No

Comments:

Randomization

☐ Yes ☐ No Randomization section was intentionally left blank.

☐ Yes ☐ No Does subject reconfirm his/her consent to participate in the study?

Randomization sequence for this subject is:


Test Visit 2 STM-1 (802)

Test Visit 3 STM-2 (101)

Test Visit 4 STM-2 (101)

Test Visit 5 STM-2 (101)

Tap here to see the randomization table


☐ Yes ☐ No Instructions were given to the subject on proper use of the smokeless tobacco product. 


☐ Yes ☐ No Subject agrees to follow those instructions during the in-clinic use.

Subject was dispensed one unit of Test Visit 2 assigned product:

STM-2 (101) by

Verified by

Subject started the sampling at : 

and completed it at : 

☐ Yes ☐ No Subject determined the study product to be acceptable and reconfirmed consent to continue study participation.

Comments: _____

Reminders

☐ Yes ☐ No Reminder section was intentionally left blank.

☐ Yes ☐ No ☐ NA Subject was provided with Cigarette Use Log for recording daily cigarette use.

☐ Yes ☐ No Subject was instructed to abstain from all tobacco and nicotine use for at least 12 hours prior to each Test Visit.

☐ Yes ☐ No Subject was instructed not to smoke or otherwise consume any tobacco or nicotine-containing product other than their UB cigarettes until study completion.

Comments:

Next Visit Information

☐ Yes ☐ No Next visit information section was intentionally left blank.

Next visit is scheduled for

/ / at :

Please update the subject randomization number
on the subject demographic page.

Comments:

☐ I have verified that this is the correct chart.

Visit Information

Visit Date

/

/



Pre-0' Mood and Physical Symptoms Scale

☐ Yes ☐ No Pre-0' Mood and Physical Symptoms Scale (MPSS) section was intentionally left blank.

☐ Yes ☐ No MPSS questionnaire data was transcribed from paper questionnaire form completed by the subject.

/

/

	Not at all	Slightly	Somewhat	Very	Extremely
1. Depressed	(1)	(2)	(3)	(4)	(5)
2. Anxious	(1)	(2)	(3)	(4)	(5)
3. Irritable	(1)	(2)	(3)	(4)	(5)
4. Restless	(1)	(2)	(3)	(4)	(5)
5. Hungry	(1)	(2)	(3)	(4)	(5)
6. Poor concentration	(1)	(2)	(3)	(4)	(5)

7. How strong is your current urge to smoke? (Check one number)

No urges	Slight	Moderate	Strong	Very strong	Extremely strong
(0)	(1)	(2)	(3)	(4)	(5)

5' Mood and Physical Symptoms Scale

☐ Yes ☐ No

5' Mood and Physical Symptoms Scale (MPSS) section was intentionally left blank.

☐ Yes ☐ No

MPSS questionnaire data was transcribed from paper questionnaire form completed by the subject.

/ /

	Not at all	Slightly	Somewhat	Very	Extremely
1. Depressed	(1)	(2)	(3)	(4)	(5)
2. Anxious	(1)	(2)	(3)	(4)	(5)
3. Irritable	(1)	(2)	(3)	(4)	(5)
4. Restless	(1)	(2)	(3)	(4)	(5)
5. Hungry	(1)	(2)	(3)	(4)	(5)
6. Poor concentration	(1)	(2)	(3)	(4)	(5)

7. How strong is your current urge to smoke? (Check one number)

No urges	Slight	Moderate	Strong	Very strong	Extremely strong
(0)	(1)	(2)	(3)	(4)	(5)

15' Mood and Physical Symptoms Scale

☐ Yes ☐ No

15' Mood and Physical Symptoms Scale (MPSS) section was intentionally left blank.

☐ Yes ☐ No

MPSS questionnaire data was transcribed from paper questionnaire form completed by the subject.

 / /

	Not at all	Slightly	Somewhat	Very	Extremely
1. Depressed	(1)	(2)	(3)	(4)	(5)
2. Anxious	(1)	(2)	(3)	(4)	(5)
3. Irritable	(1)	(2)	(3)	(4)	(5)
4. Restless	(1)	(2)	(3)	(4)	(5)
5. Hungry	(1)	(2)	(3)	(4)	(5)
6. Poor concentration	(1)	(2)	(3)	(4)	(5)

7. How strong is your current urge to smoke? (Check one number)

No urges	Slight	Moderate	Strong	Very strong	Extremely strong
(0)	(1)	(2)	(3)	(4)	(5)

30' Mood and Physical Symptoms Scale

☐ Yes ☐ No

30' Mood and Physical Symptoms Scale (MPSS) section was intentionally left blank.

☐ Yes ☐ No

MPSS questionnaire data was transcribed from paper questionnaire form completed by the subject.

/ /

	Not at all	Slightly	Somewhat	Very	Extremely
1. Depressed	(1)	(2)	(3)	(4)	(5)
2. Anxious	(1)	(2)	(3)	(4)	(5)
3. Irritable	(1)	(2)	(3)	(4)	(5)
4. Restless	(1)	(2)	(3)	(4)	(5)
5. Hungry	(1)	(2)	(3)	(4)	(5)
6. Poor concentration	(1)	(2)	(3)	(4)	(5)

7. How strong is your current urge to smoke? (Check one number)

No urges	Slight	Moderate	Strong	Very strong	Extremely strong
(0)	(1)	(2)	(3)	(4)	(5)

45' Mood and Physical Symptoms Scale

☐ Yes ☐ No

45' Mood and Physical Symptoms Scale (MPSS) section was intentionally left blank.

☐ Yes ☐ No

MPSS questionnaire data was transcribed from paper questionnaire form completed by the subject.

/ /

	Not at all	Slightly	Somewhat	Very	Extremely
1. Depressed	(1)	(2)	(3)	(4)	(5)
2. Anxious	(1)	(2)	(3)	(4)	(5)
3. Irritable	(1)	(2)	(3)	(4)	(5)
4. Restless	(1)	(2)	(3)	(4)	(5)
5. Hungry	(1)	(2)	(3)	(4)	(5)
6. Poor concentration	(1)	(2)	(3)	(4)	(5)

7. How strong is your current urge to smoke? (Check one number)

No urges	Slight	Moderate	Strong	Very strong	Extremely strong
(0)	(1)	(2)	(3)	(4)	(5)

60' Mood and Physical Symptoms Scale

☐ Yes ☐ No

60' Mood and Physical Symptoms Scale (MPSS) section was intentionally left blank.

☐ Yes ☐ No

MPSS questionnaire data was transcribed from paper questionnaire form completed by the subject.

 / /

	Not at all	Slightly	Somewhat	Very	Extremely
1. Depressed	(1)	(2)	(3)	(4)	(5)
2. Anxious	(1)	(2)	(3)	(4)	(5)
3. Irritable	(1)	(2)	(3)	(4)	(5)
4. Restless	(1)	(2)	(3)	(4)	(5)
5. Hungry	(1)	(2)	(3)	(4)	(5)
6. Poor concentration	(1)	(2)	(3)	(4)	(5)

7. How strong is your current urge to smoke? (Check one number)

No urges	Slight	Moderate	Strong	Very strong	Extremely strong
(0)	(1)	(2)	(3)	(4)	(5)

90' Mood and Physical Symptoms Scale

☐ Yes ☐ No 90' Mood and Physical Symptoms Scale (MPSS) section was intentionally left blank.

☐ Yes ☐ No MPSS questionnaire data was transcribed from paper questionnaire form completed by the subject.

/ /

	Not at all	Slightly	Somewhat	Very	Extremely
1. Depressed	(1)	(2)	(3)	(4)	(5)
2. Anxious	(1)	(2)	(3)	(4)	(5)
3. Irritable	(1)	(2)	(3)	(4)	(5)
4. Restless	(1)	(2)	(3)	(4)	(5)
5. Hungry	(1)	(2)	(3)	(4)	(5)
6. Poor concentration	(1)	(2)	(3)	(4)	(5)

7. How strong is your current urge to smoke? (Check one number)

No urges	Slight	Moderate	Strong	Very strong	Extremely strong
(0)	(1)	(2)	(3)	(4)	(5)

120' Mood and Physical Symptoms Scale

☐ Yes ☐ No

120' Mood and Physical Symptoms Scale (MPSS) section was intentionally left blank.

☐ Yes ☐ No

MPSS questionnaire data was transcribed from paper questionnaire form completed by the subject.

/ /

	Not at all	Slightly	Somewhat	Very	Extremely
1. Depressed	(1)	(2)	(3)	(4)	(5)
2. Anxious	(1)	(2)	(3)	(4)	(5)
3. Irritable	(1)	(2)	(3)	(4)	(5)
4. Restless	(1)	(2)	(3)	(4)	(5)
5. Hungry	(1)	(2)	(3)	(4)	(5)
6. Poor concentration	(1)	(2)	(3)	(4)	(5)

7. How strong is your current urge to smoke? (Check one number)

No urges	Slight	Moderate	Strong	Very strong	Extremely strong
(0)	(1)	(2)	(3)	(4)	(5)

150' Mood and Physical Symptoms Scale

☐ Yes ☐ No

150' Mood and Physical Symptoms Scale (MPSS) section was intentionally left blank.

☐ Yes ☐ No

MPSS questionnaire data was transcribed from paper questionnaire form completed by the subject.

/ /

	Not at all	Slightly	Somewhat	Very	Extremely
1. Depressed	(1)	(2)	(3)	(4)	(5)
2. Anxious	(1)	(2)	(3)	(4)	(5)
3. Irritable	(1)	(2)	(3)	(4)	(5)
4. Restless	(1)	(2)	(3)	(4)	(5)
5. Hungry	(1)	(2)	(3)	(4)	(5)
6. Poor concentration	(1)	(2)	(3)	(4)	(5)

7. How strong is your current urge to smoke? (Check one number)

No urges	Slight	Moderate	Strong	Very strong	Extremely strong
(0)	(1)	(2)	(3)	(4)	(5)

180' Mood and Physical Symptoms Scale

☐ Yes ☐ No

180' Mood and Physical Symptoms Scale (MPSS) section was intentionally left blank.

☐ Yes ☐ No

MPSS questionnaire data was transcribed from paper questionnaire form completed by the subject.

/ /

	Not at all	Slightly	Somewhat	Very	Extremely
1. Depressed	(1)	(2)	(3)	(4)	(5)
2. Anxious	(1)	(2)	(3)	(4)	(5)
3. Irritable	(1)	(2)	(3)	(4)	(5)
4. Restless	(1)	(2)	(3)	(4)	(5)
5. Hungry	(1)	(2)	(3)	(4)	(5)
6. Poor concentration	(1)	(2)	(3)	(4)	(5)

7. How strong is your current urge to smoke? (Check one number)

No urges	Slight	Moderate	Strong	Very strong	Extremely strong
(0)	(1)	(2)	(3)	(4)	(5)

☐ I have verified that this is the correct chart.

Visit Information

Visit date must be on or before the current date.

Visit Date


3	0
---	---

 /

S	e	p
---	---	---

 /

2	0	1	2
---	---	---	---



☐ Yes ☐ No Subject's ID was verified by an acceptable form of ID.

☐ Yes ☐ No UB descriptor information was confirmed.

☐ Yes ☐ No Did the subject smoke any cigarettes other than his/her UB since last visit?

☐ Yes ☐ No Did the subject use any nicotine replacement products since last visit?

☒ Yes ☐ No Did subject use any tobacco products, other than cigarettes, since last visit?

Subject should be dismissed from study.

☐ Yes ☐ No Subject continues to meet all inclusion and exclusion criteria.

Comments: _____

Adverse Events

☒ Yes ☐ No Has the subject experienced any changes in health or any changes in existing conditions since the last visit?

Please update the Adverse Event or Medical History Log.

Concomitant Medications

☒ Yes ☐ No Have there been any changes in the subject's concomitant medications since last visit?

Please update the Concomitant Medication Log.

Informed Consent

☐ Yes ☐ No Is a new version of the Informed Consent available?

☐ Yes ☐ No Was the subject given adequate time to read Informed Consent and to have his/her questions addressed prior to signing the form?

☐ Yes ☐ No Informed Consent discussion was conducted by:

☐ Yes ☐ No Informed Consent version date

/ / version number .

was voluntarily signed by subject on

/ / 

at : :

prior to any further study procedure being performed.

☐ Yes ☐ No A signed copy of the Informed Consent was given to subject for his/her records.

Comments: _____

By entering my username and password I am affixing my electronic signature to this form. I state that I have reviewed the Informed Consent form with the subject and answered any questions that the subject had.

Investigator's Signature

Vital Signs

☐ Yes ☐ No Vital signs section was intentionally left blank.

Vital signs were collected on

/ /



TIME
SEATED

TIME
MEASURED
(after seated for 5 min)

SEATED
BLOOD PRESSURE
mm/Hg

SELECTED
READING

Collection time is < 5 minutes from the time seated.

1 4 : 1 3 1 4 : 1 3 5 5 5 / 5 5 5 ☐ 1st

BP is outside protocol specified range of < or equal to 200/100 mm/Hg.

Collection time is < 5 minutes from the time seated.

1 4 : 1 3 1 4 : 1 3 5 5 5 / 5 5 5 ☐ 2nd

BP is outside protocol specified range of < or equal to 200/100 mm/Hg.

Collection time is < 5 minutes from the time seated.

1 4 : 1 3 1 4 : 1 3 5 5 5 / 5 5 5 ☐ 3rd

BP is outside protocol specified range of < or equal to 200/100 mm/Hg.

Collection time is < 5 minutes from the time seated.

1 4 : 1 3 1 4 : 1 3 5 5 5 / 5 5 5 ☐ 4th

BP is outside protocol specified range of < or equal to 200/100 mm/Hg.

Comments:

Cigarette Use Log

☐ Yes ☐ No Cigarette Use Log section was intentionally left blank.

☐ Yes ☐ No Subject returned a completed Cigarette Use Log.

☐ Yes ☐ No Data from the log was transcribed in to the table below.

Day	Date	# of cigarettes smoked today
Day 1	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 2	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 3	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 4	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 5	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 6	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 7	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>

Last cigarette extinguished by subject was
on / / at :

Comments:

Cigarette Use Log cont. (Day 8-18)

Day	Date	# of cigarettes smoked today
Day 8	<div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 9	<div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 10	<div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 11	<div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 12	<div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 13	<div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 14	<div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 15	<div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 16	<div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 17	<div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 18	<div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>

Expired Carbon Monoxide

☐ Yes


☐ No

ECO section was intentionally left blank.

ECO was performed on

/

/



SMOKERLYZER ID	TIME MEASURED	ECO	SELECTED READING
----------------	---------------	-----	------------------

:

4

3

5

☐ 1st

ECO reading is outside protocol defined range of < or equal to 12 ppm.
Subject with an ECO >12 ppm may be eligible to reschedule the test visit.

:

4

3

2

☐ 2nd

ECO reading is outside protocol defined range of < or equal to 12 ppm.
Subject with an ECO >12 ppm may be eligible to reschedule the test visit.

:

4

3

2

☐ 3rd

ECO reading is outside protocol defined range of < or equal to 12 ppm.
Subject with an ECO >12 ppm may be eligible to reschedule the test visit.

:

2

4

3


☐ 4th

ECO reading is outside protocol defined range of < or equal to 12 ppm.
Subject with an ECO >12 ppm may be eligible to reschedule the test visit.

Comments:

In-Clinic Product and MPSS Administration

☐ Yes ☐ No In-clinic product and MPSS administration section was intentionally left blank.

☐ Yes ☐ No Pre-product administration MPSS was completed by subject prior to catheter insertion at : : 







☐ Yes ☐ No Instructions were given to the subject on proper use of the smokeless tobacco product.

Subject was dispensed one unit of smokeless tobacco product:

STM-1 (802) by












Verified by

Tap here to see the randomization table

ACTION	COLLECTION WINDOW	TIME OF COLLECTION	COLLECTED IN WINDOW
Pre-0 Draw		<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> ND NA 
0' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> Yes <input type="checkbox"/> No 
Product administration start time		<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	
Product administration stop time		<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	
ACTION	COLLECTION WINDOW	TIME OF COLLECTION	COLLECTED IN WINDOW
3' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> Yes <input type="checkbox"/> No 
5' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> Yes <input type="checkbox"/> No 

ACTION	COLLECTION WINDOW	TIME OF COLLECTION	COLLECTED IN WINDOW
5' MPSS	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
7.5' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
10' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
15' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
15' MPSS	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
20' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
30' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
30' MPSS	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
45' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
45' MPSS	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No

Comments:


ACTION	COLLECTION WINDOW	TIME OF COLLECTION	COLLECTED	IN WINDOW
60' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No
60' MPSS	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No
75' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No
90' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No
90' MPSS	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No
120' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No
120' MPSS	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No
150' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No
150' MPSS	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No
180' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No
180' MPSS	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No

Comments: _____

Product Sampling

☐ Yes ☐ No Study product sampling section was intentionally left blank.

☐ Yes ☐ No Does subject reconfirm his/her consent to participate in the study?

☐ Yes ☐ No Instructions were given to the subject on proper use of the smokeless tobacco product. 


☐ Yes ☐ No Subject agrees to follow those instructions during the in-clinic use.


Subject was dispensed one unit of Test Visit 3 assigned product:

by

Verified by

Tap here to see the
randomization table

Subject started the sampling at : 

and completed it at : 

☐ Yes ☐ No Subject determined the study product to be acceptable and reconfirmed consent to continue study participation.

Comments:

Reminders

- ☐ Yes ☐ No
- Reminder section was intentionally left blank.
- ☐ Yes ☐ No ☐ NA
- Subject was provided with Cigarette Use Log for recording daily cigarette use.
- ☐ Yes ☐ No
- Subject was instructed to abstain from all tobacco and nicotine use for at least 12 hours prior to each Test Visit.
- ☐ Yes ☐ No
- Subject was instructed not to smoke or otherwise consume any tobacco or nicotine-containing product other than their UB cigarettes until study completion.

Comments:

Next Visit Information

- ☐ Yes ☐ No
- Next visit information section was intentionally left blank.
- Next visit is scheduled for

/

/

at :

Comments:

☐ I have verified that this is the correct chart.

Visit Information

Visit Date / / 

☐ Yes ☐ No Subject's ID was verified by an acceptable form of ID.

☐ Yes ☐ No UB descriptor information was confirmed.

☐ Yes ☐ No Did the subject smoke any cigarettes other than his/her UB since last visit?

☐ Yes ☐ No Did the subject use any nicotine replacement products since last visit?

☒ Yes ☐ No Did subject use any tobacco products, other than cigarettes, since last visit?

Subject should be dismissed from study.

☐ Yes ☐ No Subject continues to meet all inclusion and exclusion criteria.

Comments: _____

Adverse Events

☒ Yes ☐ No Has the subject experienced any changes in health or any changes in existing conditions since the last visit?

Please update the Adverse Event or Medical History Log.

Concomitant Medications

☒ Yes ☐ No Have there been any changes in the subject's concomitant medications since last visit?

Please update the Concomitant Medication Log.

Informed Consent

☐ Yes ☐ No Is a new version of the Informed Consent available?


☐ Yes ☐ No Was the subject given adequate time to read Informed Consent and to have his/her questions addressed prior to signing the form?

☐ Yes ☐ No Informed Consent discussion was conducted by:

☐ Yes ☐ No Informed Consent version date

/ / version number .

was voluntarily signed by subject on

/ / 

at : :

prior to any further study procedure being performed.

☐ Yes ☐ No A signed copy of the Informed Consent was given to subject for his/her records.

Comments: _____

By entering my username and password I am affixing my electronic signature to this form. I state that I have reviewed the Informed Consent form with the subject and answered any questions that the subject had.

Investigator's Signature

Vital Signs

☐ Yes ☐ No Vital signs section was intentionally left blank.

Vital signs were collected on

		/				/				
--	--	---	--	--	--	---	--	--	--	--



TIME
SEATED

TIME
MEASURED
(after seated for 5 min)

SEATED
BLOOD PRESSURE
mm/Hg

SELECTED
READING

Collection time is < 5 minutes from the time seated.

1 4 : 3 1 1 4 : 3 1 5 5 5 / 5 5 5 ☐ 1st

BP is outside protocol specified range of < or equal to 200/100 mm/Hg.

Collection time is < 5 minutes from the time seated.

1 4 : 3 1 1 4 : 3 1 5 5 5 / 5 5 5 ☐ 2nd

BP is outside protocol specified range of < or equal to 200/100 mm/Hg.

Collection time is < 5 minutes from the time seated.

1 4 : 3 1 1 4 : 3 1 5 5 5 / 5 5 5 ☐ 3rd

BP is outside protocol specified range of < or equal to 200/100 mm/Hg.

Collection time is < 5 minutes from the time seated.

1 4 : 3 1 1 4 : 3 1 5 5 5 / 5 5 5 ☐ 4th


BP is outside protocol specified range of < or equal to 200/100 mm/Hg.

Comments:

Urine Pregnancy Test

☐ Yes ☐ No ☐ NA, Male Urine pregnancy test section was intentionally left blank.

Urine sample was collected ☐ Yes ☐ No

on / / at : 

by
for urine pregnancy test ☐ Yes ☐ No

Pregnancy test was performed by

Pregnancy test results: ☒ Positive ☐ Negative

Positive pregnancy test excludes subject from study.

Investigator notes for positive pregnancy test result:

Comments:

Cigarette Use Log

☐ Yes ☐ No Cigarette Use Log section was intentionally left blank.

☐ Yes ☐ No Subject returned a completed Cigarette Use Log.

☐ Yes ☐ No Data from the log was transcribed in to the table below.

Day	Date	# of cigarettes smoked today
Day 1	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 2	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 3	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 4	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 5	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 6	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 7	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>

Last cigarette extinguished by subject was
on / / at :

Comments:

Cigarette Use Log cont. (Day 8-18)

Day	Date	# of cigarettes smoked today
Day 8	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 9	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 10	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 11	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 12	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 13	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 14	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 15	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 16	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 17	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 18	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>

Expired Carbon Monoxide


☐ Yes ☐ No

 ECO section was intentionally left blank.

ECO was performed on

/

/



SMOKERLYZER ID	TIME MEASURED	ECO	SELECTED READING
----------------	---------------	-----	------------------

:

5

5

5

☐ 1st

ECO reading is outside protocol defined range of < or equal to 12 ppm.
Subject with an ECO >12 ppm may be eligible to reschedule the test visit.

:

5

5

5

☐ 2nd

ECO reading is outside protocol defined range of < or equal to 12 ppm.
Subject with an ECO >12 ppm may be eligible to reschedule the test visit.

:

5

5

5

☐ 3rd

ECO reading is outside protocol defined range of < or equal to 12 ppm.
Subject with an ECO >12 ppm may be eligible to reschedule the test visit.

:

5

5

5


☐ 4th

ECO reading is outside protocol defined range of < or equal to 12 ppm.
Subject with an ECO >12 ppm may be eligible to reschedule the test visit.

Comments:

In-Clinic Product and MPSS Administration

☐ Yes ☐ No In-clinic product and MPSS administration section was intentionally left blank.

☐ Yes ☐ No Pre-product administration MPSS was completed by subject prior to catheter insertion at : : 







☐ Yes ☐ No Instructions were given to the subject on proper use of the smokeless tobacco product.

Subject was dispensed one unit of smokeless tobacco product:

Camel SNUS by












Verified by

Tap here to see the randomization table

ACTION	COLLECTION WINDOW	TIME OF COLLECTION	COLLECTED IN WINDOW
Pre-0 Draw		<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> 	<input type="checkbox"/> Yes <input type="checkbox"/> ND NA
0' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> 	<input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> Yes <input type="checkbox"/> No
Product administration start time <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> 			
Product administration stop time <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> 			
ACTION	COLLECTION WINDOW	TIME OF COLLECTION	COLLECTED IN WINDOW
3' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> 	<input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> Yes <input type="checkbox"/> No
5' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> 	<input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> Yes <input type="checkbox"/> No

ACTION	COLLECTION WINDOW	TIME OF COLLECTION	COLLECTED IN WINDOW
5' MPSS	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
7.5' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
10' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
15' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
15' MPSS	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
20' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
30' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
30' MPSS	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
45' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
45' MPSS	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No

Comments:


ACTION	COLLECTION WINDOW	TIME OF COLLECTION	COLLECTED	IN WINDOW
60' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No
60' MPSS	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No
75' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No
90' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No
90' MPSS	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No
120' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No
120' MPSS	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No
150' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No
150' MPSS	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No
180' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No
180' MPSS	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No

Comments: _____

Product Sampling

☐ Yes ☐ No Study product sampling section was intentionally left blank.

☐ Yes ☐ No Does subject reconfirm his/her consent to participate in the study?

☐ Yes ☐ No Instructions were given to the subject on proper use of the smokeless tobacco product. 


☐ Yes ☐ No Subject agrees to follow those instructions during the in-clinic use.


Subject was dispensed one unit of Test Visit 4 assigned product:

by

Verified by

Tap here to see the
randomization table

Subject started the sampling at : 

and completed it at : 

☐ Yes ☐ No Subject determined the study product to be acceptable and reconfirmed consent to continue study participation.

Comments:

Reminders

- ☐ Yes ☐ No Reminder section was intentionally left blank.
- ☐ Yes ☐ No ☐ NA Subject was provided with Cigarette Use Log for recording daily cigarette use.
- ☐ Yes ☐ No Subject was instructed to abstain from all tobacco and nicotine use for at least 12 hours prior to each Test Visit.
- ☐ Yes ☐ No Subject was instructed not to smoke or otherwise consume any tobacco or nicotine-containing product other than their UB cigarettes until study completion.

Comments:

Next Visit Information

- ☐ Yes ☐ No Next visit information section was intentionally left blank.
- Next visit is scheduled for

/

/

at

:

Comments:

☐ I have verified that this is the correct chart.

Visit Information

Visit date must be on or before the current date.

Visit Date


3	0
---	---

 /

S	e	p
---	---	---

 /

2	0	1	2
---	---	---	---



☐ Yes ☐ No Subject's ID was verified by an acceptable form of ID.

☐ Yes ☐ No UB descriptor information was confirmed.

☐ Yes ☐ No Did the subject smoke any cigarettes other than his/her UB since last visit?

☐ Yes ☐ No Did the subject use any nicotine replacement products since last visit?

☒ Yes ☐ No Did subject use any tobacco products, other than cigarettes, since last visit?

Subject should be dismissed from study.

☐ Yes ☐ No Subject continues to meet all inclusion and exclusion criteria.

Comments: _____

Adverse Events

☒ Yes ☐ No Has the subject experienced any changes in health or any changes in existing conditions since the last visit?

Please update the Adverse Event or Medical History Log.

Concomitant Medications

☒ Yes ☐ No Have there been any changes in the subject's concomitant medications since last visit?

Please update the Concomitant Medication Log.

Informed Consent

☐ Yes ☐ No Is a new version of the Informed Consent available?


☐ Yes ☐ No Was the subject given adequate time to read Informed Consent and to have his/her questions addressed prior to signing the form?

☐ Yes ☐ No Informed Consent discussion was conducted by:

☐ Yes ☐ No Informed Consent version date

/ / version number .

was voluntarily signed by subject on

/ / 

at : :

prior to any further study procedure being performed.

☒ Yes ☐ No A signed copy of the Informed Consent was given to subject for his/her records.

Comments: _____

By entering my username and password I am affixing my electronic signature to this form. I state that I have reviewed the Informed Consent form with the subject and answered any questions that the subject had.

 Investigator's Signature

Vital Signs

☐ Yes ☐ No Vital signs section was intentionally left blank.

Vital signs were collected on

/ /



TIME SEATED	TIME MEASURED (after seated for 5 min)	SEATED BLOOD PRESSURE mm/Hg	SELECTED READING
Collection time is < 5 minutes from the time seated.			
1 4 : 4 3	1 4 : 4 3	5 5 5 / 5 5 5	<input type="checkbox"/> 1st
BP is outside protocol specified range of < or equal to 200/100 mm/Hg.			
Collection time is < 5 minutes from the time seated.			
1 4 : 4 3	1 4 : 4 3	5 5 5 / 5 5 5	<input type="checkbox"/> 2nd
BP is outside protocol specified range of < or equal to 200/100 mm/Hg.			
Collection time is < 5 minutes from the time seated.			
1 4 : 4 3	1 4 : 4 3	5 5 5 / 5 5 5	<input type="checkbox"/> 3rd
BP is outside protocol specified range of < or equal to 200/100 mm/Hg.			
Collection time is < 5 minutes from the time seated.			
1 4 : 4 3	1 4 : 4 3	5 5 5 / 5 5 5	<input type="checkbox"/> 4th
BP is outside protocol specified range of < or equal to 200/100 mm/Hg.			

Comments:

Urine Pregnancy Test

☐ Yes ☐ No ☐ NA, Male

Urine pregnancy test section was intentionally left blank.

Urine sample was collected ☐ Yes ☐ No


on

 /

 /

 at

 :



by _____
for urine pregnancy test ☐ Yes ☐ No

Pregnancy test was performed by

Pregnancy test results: ☒ Positive ☐ Negative

Positive pregnancy test excludes subject from study.

Investigator notes for positive pregnancy test result:

Comments:

Cigarette Use Log

☐ Yes ☐ No Cigarette Use Log section was intentionally left blank.

☐ Yes ☐ No Subject returned a completed Cigarette Use Log.

☐ Yes ☐ No Data from the log was transcribed in to the table below.

Day	Date	# of cigarettes smoked today
Day 1	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 2	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 3	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 4	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 5	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 6	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 7	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>

Last cigarette extinguished by subject was
on / / at :

Comments:

Cigarette Use Log cont. (Day 8-18)

Day	Date	# of cigarettes smoked today
Day 8	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 9	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 10	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 11	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 12	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 13	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 14	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 15	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 16	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 17	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 18	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>

Expired Carbon Monoxide


☐ Yes ☐ No

 ECO section was intentionally left blank.

ECO was performed on

/

/



SMOKERLYZER ID	TIME MEASURED	ECO	SELECTED READING
----------------	---------------	-----	------------------

:

5

5

5

☐ 1st

ECO reading is outside protocol defined range of < or equal to 12 ppm.
Subject with an ECO >12 ppm may be eligible to reschedule the test visit.

:

5

5

5

☐ 2nd

ECO reading is outside protocol defined range of < or equal to 12 ppm.
Subject with an ECO >12 ppm may be eligible to reschedule the test visit.

:

5

5

5

☐ 3rd

ECO reading is outside protocol defined range of < or equal to 12 ppm.
Subject with an ECO >12 ppm may be eligible to reschedule the test visit.

:

5

5

5

☐ 4th

ECO reading is outside protocol defined range of < or equal to 12 ppm.
Subject with an ECO >12 ppm may be eligible to reschedule the test visit.

Comments:


Created:

7

Version 1.0 (Last Updated 28/Sep/2011)

In-Clinic Product and MPSS Administration

☐ Yes ☐ No In-clinic product and MPSS administration section was intentionally left blank.

☐ Yes ☐ No Pre-product administration MPSS was completed by subject prior to catheter insertion at : : 







☐ Yes ☐ No Instructions were given to the subject on proper use of the smokeless tobacco product.

Subject was dispensed one unit of smokeless tobacco product:

Camel SNUS by












Verified by

Tap here to see the randomization table

ACTION	COLLECTION WINDOW	TIME OF COLLECTION	COLLECTED IN WINDOW
Pre-0 Draw		<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> 	<input type="checkbox"/> Yes <input type="checkbox"/> ND NA
0' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> 	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
Product administration start time <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> 			
Product administration stop time <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> 			
ACTION	COLLECTION WINDOW	TIME OF COLLECTION	COLLECTED IN WINDOW
3' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> 	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
5' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> 	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No

ACTION	COLLECTION WINDOW	TIME OF COLLECTION	COLLECTED IN WINDOW
5' MPSS	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
7.5' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
10' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
15' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
15' MPSS	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
20' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
30' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
30' MPSS	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
45' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
45' MPSS	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No

Comments:


ACTION	COLLECTION WINDOW	TIME OF COLLECTION	COLLECTED	IN WINDOW
60' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No	
60' MPSS	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No	
75' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No	
90' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No	
90' MPSS	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No	
120' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No	
120' MPSS	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No	
150' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No	
150' MPSS	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No	
180' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No	
180' MPSS	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No	

Comments: _____

Product Sampling

☐ Yes ☐ No Study product sampling section was intentionally left blank.

☐ Yes ☐ No Does subject reconfirm his/her consent to participate in the study?

☐ Yes ☐ No Instructions were given to the subject on proper use of the smokeless tobacco product. 


☐ Yes ☐ No Subject agrees to follow those instructions during the in-clinic use.


Subject was dispensed one unit of Test Visit 5 assigned product:

Camel SNUS by

Verified by

Tap here to see the
randomization table

Subject started the sampling at : 

and completed it at : 

☐ Yes ☐ No Subject determined the study product to be acceptable and reconfirmed consent to continue study participation.

Comments:

Reminders

- ☐ Yes ☐ No Reminder section was intentionally left blank.
- ☐ Yes ☐ No ☐ NA Subject was provided with Cigarette Use Log for recording daily cigarette use.
- ☐ Yes ☐ No Subject was instructed to abstain from all tobacco and nicotine use for at least 12 hours prior to each Test Visit.
- ☐ Yes ☐ No Subject was instructed not to smoke or otherwise consume any tobacco or nicotine-containing product other than their UB cigarettes until study completion.

Comments:

Next Visit Information

- ☐ Yes ☐ No Next visit information section was intentionally left blank.
- Next visit is scheduled for

/

/

at :

Comments:

☐ I have verified that this is the correct chart.

Visit Information

Visit date must be on or before the current date.

Visit Date


3	0
---	---

 /

S	e	p
---	---	---

 /

2	0	1	2
---	---	---	---



☐ Yes ☐ No Subject's ID was verified by an acceptable form of ID.

☐ Yes ☐ No UB descriptor information was confirmed.

☐ Yes ☐ No Did the subject smoke any cigarettes other than his/her UB since last visit?

☐ Yes ☐ No Did the subject use any nicotine replacement products since last visit?

☒ Yes ☐ No Did subject use any tobacco products, other than cigarettes, since last visit?

Subject should be dismissed from study.

☐ Yes ☐ No Subject continues to meet all inclusion and exclusion criteria.

Comments: _____

Adverse Events

☒ Yes ☐ No Has the subject experienced any changes in health or any changes in existing conditions since the last visit?

Please update the Adverse Event or Medical History Log.

Concomitant Medications

☒ Yes ☐ No Have there been any changes in the subject's concomitant medications since last visit?

Please update the Concomitant Medication Log.

Informed Consent

☐ Yes ☐ No Is a new version of the Informed Consent available?


☐ Yes ☐ No Was the subject given adequate time to read Informed Consent and to have his/her questions addressed prior to signing the form?

☐ Yes ☐ No Informed Consent discussion was conducted by:

☐ Yes ☐ No Informed Consent version date

/ / version number .

was voluntarily signed by subject on

/ / 

at : :

prior to any further study procedure being performed.

☐ Yes ☐ No A signed copy of the Informed Consent was given to subject for his/her records.

Comments: _____

By entering my username and password I am affixing my electronic signature to this form. I state that I have reviewed the Informed Consent form with the subject and answered any questions that the subject had.

Investigator's Signature

Vital Signs

☐ Yes ☐ No Vital signs section was intentionally left blank.

Vital signs were collected on

/ /



TIME
SEATED

TIME
MEASURED
(after seated for 5 min)

SEATED
BLOOD PRESSURE
mm/Hg

SELECTED
READING

Collection time is < 5 minutes from the time seated.

1 4 : 4 7 1 4 : 4 7 5 5 5 / 5 5 5 ☐ 1st

BP is outside protocol specified range of < or equal to 200/100 mm/Hg.

Collection time is < 5 minutes from the time seated.

1 4 : 4 7 1 4 : 4 7 5 5 5 / 5 5 5 ☐ 2nd

BP is outside protocol specified range of < or equal to 200/100 mm/Hg.

Collection time is < 5 minutes from the time seated.

1 4 : 4 7 1 4 : 4 7 5 5 5 / 5 5 5 ☐ 3rd

BP is outside protocol specified range of < or equal to 200/100 mm/Hg.

Collection time is < 5 minutes from the time seated.

1 4 : 4 7 1 4 : 4 7 5 5 5 / 5 5 5 ☐ 4th

BP is outside protocol specified range of < or equal to 200/100 mm/Hg.

TIME SEATED

TIME MEASURED
(after seated for 5 min)

HEART RATE

1 4 : 4 7

1 4 : 4 7

5 5 5

Collection time is < 5 minutes from the time seated.

Oral temperature

.

☒ F° ☐ C°

Cigarette Use Log

☐ Yes ☐ No Cigarette Use Log section was intentionally left blank.

☐ Yes ☐ No Subject returned a completed Cigarette Use Log.

☐ Yes ☐ No Data from the log was transcribed in to the table below.

Day	Date	# of cigarettes smoked today
Day 1	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 2	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 3	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 4	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 5	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 6	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 7	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>

Last cigarette extinguished by subject was
on / / at :

Comments:

Cigarette Use Log cont. (Day 8-18)

Day	Date	# of cigarettes smoked today
Day 8	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 9	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 10	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 11	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 12	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 13	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 14	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 15	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 16	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 17	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 18	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>

Expired Carbon Monoxide

☐ Yes


☐ No

ECO section was intentionally left blank.

ECO was performed on

/

/



SMOKERLYZER ID	TIME MEASURED	ECO	SELECTED READING
----------------	---------------	-----	------------------

:

5

5

5

☐ 1st

ECO reading is outside protocol defined range of < or equal to 12 ppm.
Subject with an ECO >12 ppm may be eligible to reschedule the test visit.

:

5

5

5

☐ 2nd

ECO reading is outside protocol defined range of < or equal to 12 ppm.
Subject with an ECO >12 ppm may be eligible to reschedule the test visit.

:

5

5

5

☐ 3rd

ECO reading is outside protocol defined range of < or equal to 12 ppm.
Subject with an ECO >12 ppm may be eligible to reschedule the test visit.

:

5

5

5


☐ 4th

ECO reading is outside protocol defined range of < or equal to 12 ppm.
Subject with an ECO >12 ppm may be eligible to reschedule the test visit.

Comments:

In-Clinic Product and MPSS Administration

☐ Yes ☐ No In-clinic product and MPSS administration section was intentionally left blank.

☐ Yes ☐ No Pre-product administration MPSS was completed by subject prior to catheter insertion at : : 







☐ Yes ☐ No Instructions were given to the subject on proper use of the smokeless tobacco product.

Subject was dispensed one unit of smokeless tobacco product:

Camel SNUS by












Verified by

Tap here to see the randomization table

ACTION	COLLECTION WINDOW	TIME OF COLLECTION	COLLECTED IN WINDOW
Pre-0 Draw		<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> 	<input type="checkbox"/> Yes <input type="checkbox"/> ND NA
0' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> 	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
Product administration start time <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> 			
Product administration stop time <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> 			
ACTION	COLLECTION WINDOW	TIME OF COLLECTION	COLLECTED IN WINDOW
3' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> 	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
5' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> 	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No

ACTION	COLLECTION WINDOW	TIME OF COLLECTION	COLLECTED IN WINDOW
5' MPSS	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
7.5' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
10' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
15' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
15' MPSS	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
20' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
30' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
30' MPSS	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
45' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
45' MPSS	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No

Comments:

ACTION	COLLECTION WINDOW	TIME OF COLLECTION	COLLECTED	IN WINDOW
60' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No
60' MPSS	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No
75' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No
90' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No
90' MPSS	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No
120' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No
120' MPSS	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No
150' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No
150' MPSS	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No
180' Draw	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No
180' MPSS	00:00:00 - 00:00:00	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No

Comments: _____

Reminders

- ☐ Yes ☐ No Reminder section was intentionally left blank.
- ☐ Yes ☐ No ☐ NA Subject was provided with Cigarette Use Log for recording daily cigarette use.
- ☐ Yes ☐ No Subject was instructed to abstain from all tobacco and nicotine use for at least 12 hours prior to each Test Visit.
- ☐ Yes ☐ No Subject was instructed not to smoke or otherwise consume any tobacco or nicotine-containing product other than their UB cigarettes until study completion.

Comments:

Next Visit Information

- ☐ Yes ☐ No Next visit information section was intentionally left blank.
- Next visit is scheduled for

/

/

at

:

Comments:

☐ I have verified that this is the correct chart.

Visit Information

Visit Date / / 

☐ Yes ☐ No Subject's ID was verified by an acceptable form of ID.

☐ Yes ☐ No UB descriptor information was confirmed.

☒ Yes ☐ No Did the subject smoke any cigarettes other than his/her UB since last visit?

☐ Yes ☐ No Did the subject use any nicotine replacement products since last visit?

☐ Yes ☐ No Did subject use any tobacco products, other than cigarettes, since last visit?

Subject should be dismissed from study.

☐ Yes ☐ No Subject continues to meet all inclusion and exclusion criteria.

Comments: _____

Adverse Events

☒ Yes ☐ No Has the subject experienced any changes in health or any changes in existing conditions since the last visit?

Please update the Adverse Event or Medical History Log.

Concomitant Medications

☒ Yes ☐ No Have there been any changes in the subject's concomitant medications since last visit?

Please update the Concomitant Medication Log.

Informed Consent

☐ Yes ☐ No Is a new version of the Informed Consent available?


☐ Yes ☐ No Was the subject given adequate time to read Informed Consent and to have his/her questions addressed prior to signing the form?

☐ Yes ☐ No Informed Consent discussion was conducted by:

☐ Yes ☐ No Informed Consent version date

/ / version number .

was voluntarily signed by subject on

/ / 

at : :

prior to any further study procedure being performed.

☐ Yes ☐ No A signed copy of the Informed Consent was given to subject for his/her records.

Comments: _____

By entering my username and password I am affixing my electronic signature to this form. I state that I have reviewed the Informed Consent form with the subject and answered any questions that the subject had.

Investigator's Signature

Vital Signs

☐ Yes ☐ No Vital signs section was intentionally left blank.

Vital signs were collected on / /



TIME
SEATED

TIME
MEASURED
(after seating for 5 min)

SEATED
BLOOD PRESSURE
mm/Hg

SELECTED
READING

Collection time is < 5 minutes from the time seated.

15 : 10 15 : 10 201 / ☐ 1st

BP is outside protocol specified range of < or equal to 200/100 mm/Hg.

Collection time is < 5 minutes from the time seated.

15 : 10 15 : 10 201 / ☐ 2nd

BP is outside protocol specified range of < or equal to 200/100 mm/Hg.

Collection time is < 5 minutes from the time seated.

15 : 10 15 : 10 201 / ☐ 3rd

BP is outside protocol specified range of < or equal to 200/100 mm/Hg.

Collection time is < 5 minutes from the time seated.

15 : 10 15 : 10 201 / ☐ 4th

BP is outside protocol specified range of < or equal to 200/100 mm/Hg.

TIME SEATED

TIME MEASURED
(after seating for 5 min)

HEART RATE

15 : 10 15 : 10


Collection time is < 5 minutes from the time seated.

Oral temperature 9 8 . 7 ☒ F° ☐ C° 37.1 Degrees C

Urine Drug and Pregnancy Test

☐ Yes ☐ No Urine pregnancy test section was intentionally left blank.

Urine sample was collected ☐ Yes ☐ No

on / / at : 

by

for: Urine drug test ☐ Yes ☐ No

Urine pregnancy test ☐ Yes ☐ No ☐ NA, Male

Drug test was performed by

Drug Screen test results: ☒ Positive ☐ Negative

Positive urine drug screen may exclude subject from study.

Investigator notes for positive drug test result:

Pregnancy test was performed by

Pregnancy test results: ☒ Positive ☐ Negative

Positive pregnancy test excludes subject from study.

Investigator notes for positive pregnancy test result:

Comments: _____

Cigarette Use Log

☐ Yes ☐ No Cigarette Use Log section was intentionally left blank.

☐ Yes ☐ No Subject returned a completed Cigarette Use Log.

☐ Yes ☐ No Data from the log was transcribed in to the table below.

Day	Date	# of cigarettes smoked today
Day 1	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 2	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 3	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 4	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 5	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 6	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 7	<div><div></div><div></div></div> / <div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>

Last cigarette extinguished by subject was
on / / at :

Comments: _____

Cigarette Use Log cont. (Day 8-18)

Day	Date	# of cigarettes smoked today
Day 8	<div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 9	<div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 10	<div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 11	<div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 12	<div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 13	<div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 14	<div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 15	<div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 16	<div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 17	<div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>
Day 18	<div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div></div> / <div><div></div><div></div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div>

Expired Carbon Monoxide


☐ Yes ☐ No

 ECO section was intentionally left blank.

ECO was performed on

/

/




SMOKERLYZER ID	TIME MEASURED	ECO	SELECTED READING
<div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div> : <div><div></div><div></div></div>	<div><div>0</div><div>2</div><div>0</div></div>	<input type="checkbox"/> 1st
ECO reading is outside protocol defined range of < or equal to 12 ppm. Subject with an ECO >12 ppm may be eligible to reschedule the test visit.			
<div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div> : <div><div></div><div></div></div>	<div><div>0</div><div>2</div><div>0</div></div>	<input type="checkbox"/> 2nd
ECO reading is outside protocol defined range of < or equal to 12 ppm. Subject with an ECO >12 ppm may be eligible to reschedule the test visit.			
<div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div> : <div><div></div><div></div></div>	<div><div>0</div><div>2</div><div>0</div></div>	<input type="checkbox"/> 3rd
ECO reading is outside protocol defined range of < or equal to 12 ppm. Subject with an ECO >12 ppm may be eligible to reschedule the test visit.			
<div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div></div> : <div><div></div><div></div></div>	<div><div>0</div><div>2</div><div>0</div></div>	<input type="checkbox"/> 4th
ECO reading is outside protocol defined range of < or equal to 12 ppm. Subject with an ECO >12 ppm may be eligible to reschedule the test visit.			

Comments:

In-Clinic Product and MPSS Administration

☐ Yes ☐ No In-clinic product and MPSS administration section was intentionally left blank.

☐ Yes ☐ No Pre-product administration MPSS was completed by subject prior to catheter insertion at : : 







☐ Yes ☐ No Instructions were given to the subject on proper use of the smokeless tobacco product.

Subject was dispensed one unit of disolvable tobacco product:

STM-1 (802) by












Verified by

Tap here to see the randomization table

ACTION	COLLECTION WINDOW	TIME OF COLLECTION	COLLECTED IN WINDOW
Pre-0 Draw		<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> 	<input type="checkbox"/> Yes <input type="checkbox"/> ND NA
0' Draw	15:10:58 - 15:11:58	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> 	<input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> Yes <input type="checkbox"/> No
Product administration start time		<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> 	
Product administration stop time		<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> 	
ACTION	COLLECTION WINDOW	TIME OF COLLECTION	COLLECTED IN WINDOW
3' Draw	15:13:58 - 15:14:58	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> 	<input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> Yes <input type="checkbox"/> No
5' Draw	15:15:58 - 15:16:58	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> 	<input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> Yes <input type="checkbox"/> No

ACTION	COLLECTION WINDOW	TIME OF COLLECTION	COLLECTED IN WINDOW
5' MPSS	15:16:28 - 15:17:28	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
7.5' Draw	15:18:28 - 15:19:28	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
10' Draw	15:20:58 - 15:21:58	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
15' Draw	15:25:58 - 15:26:58	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
15' MPSS	15:26:28 - 15:27:28	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
20' Draw	15:30:58 - 15:31:58	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
30' Draw	15:40:58 - 15:41:58	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
30' MPSS	15:41:28 - 15:42:28	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
45' Draw	15:55:58 - 15:56:58	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No
45' MPSS	15:56:28 - 15:57:28	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> ND <input type="checkbox"/> No

Comments:


ACTION	COLLECTION WINDOW	TIME OF COLLECTION	COLLECTED	IN WINDOW
60' Draw	16:10:58 - 16:11:58	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No
60' MPSS	16:11:28 - 16:13:28	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No
75' Draw	16:25:58 - 16:26:58	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No
90' Draw	16:40:58 - 16:41:58	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No
90' MPSS	16:41:28 - 16:43:28	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No
120' Draw	17:09:28 - 17:13:28	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No
120' MPSS	17:11:28 - 17:13:28	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No
150' Draw	17:39:28 - 17:43:28	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No
150' MPSS	17:41:28 - 17:46:28	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No
180' Draw	18:09:28 - 18:13:28	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No
180' MPSS	18:11:28 - 18:16:28	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	 <input type="checkbox"/> Yes <input type="checkbox"/> ND	<input type="checkbox"/> Yes <input type="checkbox"/> No

Comments:

Product Sampling

☐ Yes ☐ No Study product sampling section was intentionally left blank.

☐ Yes ☐ No Does subject reconfirm his/her consent to participate in the study?

☐ Yes ☐ No Instructions were given to the subject on proper use of the smokeless tobacco product. 


☐ Yes ☐ No Subject agrees to follow those instructions during the in-clinic use.


Subject was dispensed one unit of Test Visit 3 assigned product:

STM-1 (802) by

Verified by

Tap here to see the
randomization table

Subject started the sampling at : 

and completed it at : 

☐ Yes ☐ No Subject determined the study product to be acceptable and reconfirmed consent to continue study participation.

Comments:

Reminders

- ☐ Yes ☐ No Reminder section was intentionally left blank.
- ☐ Yes ☐ No ☐ NA Subject was provided with Cigarette Use Log for recording daily cigarette use.
- ☐ Yes ☐ No Subject was instructed to abstain from all tobacco and nicotine use for at least 12 hours prior to each Test Visit.
- ☐ Yes ☐ No Subject was instructed not to smoke or otherwise consume any tobacco or nicotine-containing product other than their UB cigarettes until study completion.

Comments:

Next Visit Information

- ☐ Yes ☐ No Next visit information section was intentionally left blank.
- Next visit is scheduled for

/

/

at

:

Comments:

Pre-0 Mood and Physical Symptoms Scale

☐ Yes ☐ No Pre-0 Mood and Physical Symptoms Scale (MPSS) section was intentionally left blank.

☐ Yes ☐ No MPSS test data was transcribed from paper test form completed by the subject on:

 / /

	Not at all	Slightly	Somewhat	Very	Extremely
1. Depressed	①	②	③	④	⑤
2. Anxious	①	②	③	④	⑤
3. Irritable	①	②	③	④	⑤
4. Restless	①	②	③	④	⑤
5. Hungry	①	②	③	④	⑤
6. Poor concentration	①	②	③	④	⑤

7. How strong is your current urge to smoke? (Check one number)

No urges	Slight	Moderate	Strong	Very strong	Extremely strong
①0	①1	①2	①3	①4	①5

5' Mood and Physical Symptoms Scale

☐ Yes ☐ No

5' Mood and Physical Symptoms Scale (MPSS) section was intentionally left blank.

☐ Yes ☐ No

MPSS test data was transcribed from paper test form completed by the subject on:

 / /

	Not at all	Slightly	Somewhat	Very	Extremely
1. Depressed	(1)	(2)	(3)	(4)	(5)
2. Anxious	(1)	(2)	(3)	(4)	(5)
3. Irritable	(1)	(2)	(3)	(4)	(5)
4. Restless	(1)	(2)	(3)	(4)	(5)
5. Hungry	(1)	(2)	(3)	(4)	(5)
6. Poor concentration	(1)	(2)	(3)	(4)	(5)

7. How strong is your current urge to smoke? (Check one number)

No urges	Slight	Moderate	Strong	Very strong	Extremely strong
(0)	(1)	(2)	(3)	(4)	(5)

15' Mood and Physical Symptoms Scale

☐ Yes ☐ No

15' Mood and Physical Symptoms Scale (MPSS) section was intentionally left blank.

☐ Yes ☐ No

MPSS test data was transcribed from paper test form completed by the subject on:

/ /

	Not at all	Slightly	Somewhat	Very	Extremely
1. Depressed	(1)	(2)	(3)	(4)	(5)
2. Anxious	(1)	(2)	(3)	(4)	(5)
3. Irritable	(1)	(2)	(3)	(4)	(5)
4. Restless	(1)	(2)	(3)	(4)	(5)
5. Hungry	(1)	(2)	(3)	(4)	(5)
6. Poor concentration	(1)	(2)	(3)	(4)	(5)

7. How strong is your current urge to smoke? (Check one number)

No urges	Slight	Moderate	Strong	Very strong	Extremely strong
(0)	(1)	(2)	(3)	(4)	(5)

30' Mood and Physical Symptoms Scale

☐ Yes ☐ No

30' Mood and Physical Symptoms Scale (MPSS) section was intentionally left blank.

☐ Yes ☐ No

MPSS test data was transcribed from paper test form completed by the subject on:

/ /

	Not at all	Slightly	Somewhat	Very	Extremely
1. Depressed	(1)	(2)	(3)	(4)	(5)
2. Anxious	(1)	(2)	(3)	(4)	(5)
3. Irritable	(1)	(2)	(3)	(4)	(5)
4. Restless	(1)	(2)	(3)	(4)	(5)
5. Hungry	(1)	(2)	(3)	(4)	(5)
6. Poor concentration	(1)	(2)	(3)	(4)	(5)

7. How strong is your current urge to smoke? (Check one number)

No urges	Slight	Moderate	Strong	Very strong	Extremely strong
(0)	(1)	(2)	(3)	(4)	(5)

45' Mood and Physical Symptoms Scale

☐ Yes ☐ No

45' Mood and Physical Symptoms Scale (MPSS) section was intentionally left blank.

☐ Yes ☐ No

MPSS test data was transcribed from paper test form completed by the subject on:

/ /

	Not at all	Slightly	Somewhat	Very	Extremely
1. Depressed	(1)	(2)	(3)	(4)	(5)
2. Anxious	(1)	(2)	(3)	(4)	(5)
3. Irritable	(1)	(2)	(3)	(4)	(5)
4. Restless	(1)	(2)	(3)	(4)	(5)
5. Hungry	(1)	(2)	(3)	(4)	(5)
6. Poor concentration	(1)	(2)	(3)	(4)	(5)

7. How strong is your current urge to smoke? (Check one number)

No urges	Slight	Moderate	Strong	Very strong	Extremely strong
(0)	(1)	(2)	(3)	(4)	(5)

60' Mood and Physical Symptoms Scale

☐ Yes ☐ No

60' Mood and Physical Symptoms Scale (MPSS) section was intentionally left blank.

☐ Yes ☐ No

MPSS test data was transcribed from paper test form completed by the subject on:

/ /

	Not at all	Slightly	Somewhat	Very	Extremely
1. Depressed	(1)	(2)	(3)	(4)	(5)
2. Anxious	(1)	(2)	(3)	(4)	(5)
3. Irritable	(1)	(2)	(3)	(4)	(5)
4. Restless	(1)	(2)	(3)	(4)	(5)
5. Hungry	(1)	(2)	(3)	(4)	(5)
6. Poor concentration	(1)	(2)	(3)	(4)	(5)

7. How strong is your current urge to smoke? (Check one number)

No urges	Slight	Moderate	Strong	Very strong	Extremely strong
(0)	(1)	(2)	(3)	(4)	(5)

90' Mood and Physical Symptoms Scale

☐ Yes ☐ No

90' Mood and Physical Symptoms Scale (MPSS) section was intentionally left blank.

☐ Yes ☐ No

MPSS test data was transcribed from paper test form completed by the subject on:

/ /

	Not at all	Slightly	Somewhat	Very	Extremely
1. Depressed	(1)	(2)	(3)	(4)	(5)
2. Anxious	(1)	(2)	(3)	(4)	(5)
3. Irritable	(1)	(2)	(3)	(4)	(5)
4. Restless	(1)	(2)	(3)	(4)	(5)
5. Hungry	(1)	(2)	(3)	(4)	(5)
6. Poor concentration	(1)	(2)	(3)	(4)	(5)

7. How strong is your current urge to smoke? (Check one number)

No urges	Slight	Moderate	Strong	Very strong	Extremely strong
(0)	(1)	(2)	(3)	(4)	(5)

120' Mood and Physical Symptoms Scale

☐ Yes ☐ No

120' Mood and Physical Symptoms Scale (MPSS) section was intentionally left blank.

☐ Yes ☐ No

MPSS test data was transcribed from paper test form completed by the subject on:

/ /

	Not at all	Slightly	Somewhat	Very	Extremely
1. Depressed	(1)	(2)	(3)	(4)	(5)
2. Anxious	(1)	(2)	(3)	(4)	(5)
3. Irritable	(1)	(2)	(3)	(4)	(5)
4. Restless	(1)	(2)	(3)	(4)	(5)
5. Hungry	(1)	(2)	(3)	(4)	(5)
6. Poor concentration	(1)	(2)	(3)	(4)	(5)

7. How strong is your current urge to smoke? (Check one number)

No urges	Slight	Moderate	Strong	Very strong	Extremely strong
(0)	(1)	(2)	(3)	(4)	(5)

150' Mood and Physical Symptoms Scale

☐ Yes ☐ No

150' Mood and Physical Symptoms Scale (MPSS) section was intentionally left blank.

☐ Yes ☐ No

MPSS test data was transcribed from paper test form completed by the subject on:

/ /

	Not at all	Slightly	Somewhat	Very	Extremely
1. Depressed	(1)	(2)	(3)	(4)	(5)
2. Anxious	(1)	(2)	(3)	(4)	(5)
3. Irritable	(1)	(2)	(3)	(4)	(5)
4. Restless	(1)	(2)	(3)	(4)	(5)
5. Hungry	(1)	(2)	(3)	(4)	(5)
6. Poor concentration	(1)	(2)	(3)	(4)	(5)

7. How strong is your current urge to smoke? (Check one number)

No urges	Slight	Moderate	Strong	Very strong	Extremely strong
(0)	(1)	(2)	(3)	(4)	(5)

180' Mood and Physical Symptoms Scale

☐ Yes ☐ No

180' Mood and Physical Symptoms Scale (MPSS) section was intentionally left blank.

☐ Yes ☐ No

MPSS test data was transcribed from paper test form completed by the subject on:

/ /

	Not at all	Slightly	Somewhat	Very	Extremely
1. Depressed	(1)	(2)	(3)	(4)	(5)
2. Anxious	(1)	(2)	(3)	(4)	(5)
3. Irritable	(1)	(2)	(3)	(4)	(5)
4. Restless	(1)	(2)	(3)	(4)	(5)
5. Hungry	(1)	(2)	(3)	(4)	(5)
6. Poor concentration	(1)	(2)	(3)	(4)	(5)

7. How strong is your current urge to smoke? (Check one number)

No urges	Slight	Moderate	Strong	Very strong	Extremely strong
(0)	(1)	(2)	(3)	(4)	(5)

Visit Information

Adverse Events

Please update the Adverse Event or Medical History Log.

Concomitant Medications

Please update the Concomitant Medication Log.

Informed Consent

☐ Yes ☐ No ☐ NA Is a new version of the Informed Consent available?
NA if collected at Test Visit 5.


☐ Yes ☐ No Was the subject given adequate time to read Informed Consent
and to have his/her questions addressed prior to signing the
form?

☐ Yes ☐ No Informed Consent discussion was conducted by:

☐ Yes ☐ No Informed Consent version date

/ / version number .

was voluntarily signed by subject on

/ / 

at : :

prior to any further study procedure being performed.

☐ Yes ☐ No A signed copy of the Informed Consent was given to subject for
his/her records.

Comments: _____

By entering my username and password I am affixing my electronic signature to this form. I state
that I have reviewed the Informed Consent form with the subject and answered any questions
that the subject had.

Investigator's Signature

Vital Signs

☐ Yes ☐ No Vital signs section was intentionally left blank.

Vital signs were collected on / / 



TIME
SEATED

TIME
MEASURED
(after seating for 5 min)

SEATED
BLOOD PRESSURE
mm/Hg



SELECTED
READING

Collection time is < 5 minutes from the time seated.

14 : 00  14 : 00  201 / 101 ☐ 1st



Blood pressure is outside protocol specified range of 200/100 mm/Hg.

Collection time is < 5 minutes from the time seated.

14 : 00  14 : 00  201 / 101 ☐ 2nd



Blood pressure is outside protocol specified range of 200/100 mm/Hg.

Collection time is < 5 minutes from the time seated.



14 : 00  14 : 00  211 / ☐ 3rd

Blood pressure is outside protocol specified range of 200/100 mm/Hg.

Collection time is < 5 minutes from the time seated.

14 : 00  14 : 00  / 101 ☐ 4th

Blood pressure is outside protocol specified range of 200/100 mm/Hg.

14 : 00  14 : 00  Heart Rate

Oral temperature 98 . 7 ☒ F° ☐ C° 37.1 Degrees C

Physical and Oral Examination

☐ Yes ☐ No Physical and oral examination section was intentionally left blank.

Weight: . lbs Height: . in

Physical and Oral Examination cont.

SITE/SYSTEM	If Abn, specify CS or NCS and record symptoms/diagnosis	
Heart	<input type="checkbox"/> nl <input type="checkbox"/> abn <input type="checkbox"/> nd	<input type="checkbox"/> CS _____ <input type="checkbox"/> NCS _____
		<input type="checkbox"/> CS _____ <input type="checkbox"/> NCS _____
Lungs	<input type="checkbox"/> nl <input type="checkbox"/> abn <input type="checkbox"/> nd	<input type="checkbox"/> CS _____ <input type="checkbox"/> NCS _____
		<input type="checkbox"/> CS _____ <input type="checkbox"/> NCS _____
Abdomen	<input type="checkbox"/> nl <input type="checkbox"/> abn <input type="checkbox"/> nd	<input type="checkbox"/> CS _____ <input type="checkbox"/> NCS _____
		<input type="checkbox"/> CS _____ <input type="checkbox"/> NCS _____
Skin	<input type="checkbox"/> nl <input type="checkbox"/> abn <input type="checkbox"/> nd	<input type="checkbox"/> CS _____ <input type="checkbox"/> NCS _____
		<input type="checkbox"/> CS _____ <input type="checkbox"/> NCS _____
Ears/Nose/ Throat (ENT)	<input type="checkbox"/> nl <input type="checkbox"/> abn <input type="checkbox"/> nd	<input type="checkbox"/> CS _____ <input type="checkbox"/> NCS _____
		<input type="checkbox"/> CS _____ <input type="checkbox"/> NCS _____

Physical and Oral Examination cont.

SITE/SYSTEM	If Abn, specify CS or NCS and record symptoms/diagnosis	
Neck	<input type="checkbox"/> nl <input type="checkbox"/> abn <input type="checkbox"/> nd	<input type="checkbox"/> cs _____ <input type="checkbox"/> ncs _____ <input type="checkbox"/> cs _____ <input type="checkbox"/> ncs _____
Evidence of leukoplakia	<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> nd	<input type="checkbox"/> cs _____ <input type="checkbox"/> ncs _____ <input type="checkbox"/> cs _____ <input type="checkbox"/> ncs _____
Evidence of other oral keratosis	<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> nd	<input type="checkbox"/> cs _____ <input type="checkbox"/> ncs _____ <input type="checkbox"/> cs _____ <input type="checkbox"/> ncs _____
Evidence of oral lesions	<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> nd	<input type="checkbox"/> cs _____ <input type="checkbox"/> ncs _____ <input type="checkbox"/> cs _____ <input type="checkbox"/> ncs _____

Comments: _____

By entering my username and password I am affixing my electronic signature to this form. I state that I have conducted a complete physical examination (per the protocol) of this subject and have identified and noted, to the best of my ability, any significant abnormalities that may preclude this subject from safely completing the trial.

Physician Signature

Study Discharge

☐ Yes ☐ No Study discharge section was intentionally left blank.

Subject: ☐ completed and has been discharged from study
☐ withdrew from study

Reason for withdrawal:

☐ Adverse Event, specify

☐ Protocol noncompliance, specify

☐ Consent withdrawn

☐ Pregnancy

☐ Inability to communicate and/or unwillingness to cooperate with the investigator, specify

☐ Lost to follow up

☐ Change in status with the respect to an inclusion/exclusion criterion that is clinically relevant and/or could affect subject safety, specify

☐ Other, specify

Comments:

By entering my username and password I am affixing my electronic signature, affirming that I have reviewed subject's study discharge.

Physician Signature

☐ I have verified that this is the correct chart.

Visit Information

Visit date must be on or before the current date.

Visit Date

30 / Sep / 2012



Comprehensive Metabolic Profile (CMP)

☐ Yes ☐ No Comprehensive metabolic (CMP) test results data captured.

CMP test accession number:

was

reported by Solstas Lab Partners on

/

/

TEST NAME	RESULT	RATING
Sodium	<div></div> mEq/L	<input type="checkbox"/> cs <input type="checkbox"/> ncs
Potassium	<div></div> mEq/L	<input type="checkbox"/> cs <input type="checkbox"/> ncs
Chloride	<div></div> mEq/L	<input type="checkbox"/> cs <input type="checkbox"/> ncs
Chloride value meets alert value level of < 65 mEq/L or > 130 mEq/L.		
Carbon Dioxide (CO2)	<div></div> mEq/L	<input type="checkbox"/> cs <input type="checkbox"/> ncs
Glucose	<div></div> mg/dL	<input type="checkbox"/> cs <input type="checkbox"/> ncs
BUN	<div></div> mg/dL	<input type="checkbox"/> cs <input type="checkbox"/> ncs

Comprehensive Metabolic Profile (CMP) cont.

TEST NAME	RESULT	RATING
Creatinine	<input type="checkbox"/> Male <input type="checkbox"/> Female <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/> mg/dL	<input type="checkbox"/> cs <input type="checkbox"/> ncs
Bilirubin, Total	<input type="text"/> <input type="text"/> . <input type="text"/> mg/dL	<input type="checkbox"/> cs <input type="checkbox"/> ncs
Alkaline Phosphatase	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> U/L	<input type="checkbox"/> cs <input type="checkbox"/> ncs
AST/SGOT	<input type="text"/> <input type="text"/> <input type="text"/> U/L	<input type="checkbox"/> cs <input type="checkbox"/> ncs
ALT/SGPT	<input type="checkbox"/> Male <input type="checkbox"/> Female <input type="text"/> <input type="text"/> <input type="text"/> U/L	<input type="checkbox"/> cs <input type="checkbox"/> ncs
Total Protein	<input type="text"/> <input type="text"/> . <input type="text"/> g/dL	<input type="checkbox"/> cs <input type="checkbox"/> ncs
Albumin	<input type="text"/> 1 . 1 g/dL	<input type="checkbox"/> cs <input type="checkbox"/> ncs
Albumin value meets alert value level of less than 2.0 g/dL.		
Calcium	<input type="text"/> <input type="text"/> 0 . 1 mg/dL	<input type="checkbox"/> cs <input type="checkbox"/> ncs
Calcium value meets critical value level of < 6.5 mg/dL or > 13.0 mg/dL.		
Cholesterol	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mg/dL	<input type="checkbox"/> cs <input type="checkbox"/> ncs
Triglyceride	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mg/dL	<input type="checkbox"/> cs <input type="checkbox"/> ncs

Complete Blood Count (CBC)

☐ Yes ☐ No Complete blood count (CBC) test results data captured.

CBC test accession number was

reported by Solstas Lab Partners on / /

TEST NAME	RESULT	RATING
WBC	<input type="text"/> <input type="text"/> <input type="text"/> 0 . <input type="text"/> 1 K/uL	<input type="checkbox"/> cs <input type="checkbox"/> ncs
WBC value meets alert value level of < 1 .5 K/uL or > 50 K/uL.		
RBC	<input checked="" type="checkbox"/> Male <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/> <input type="checkbox"/> Female	<input type="checkbox"/> cs <input type="checkbox"/> ncs
Hemoglobin	<input type="checkbox"/> Male <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="checkbox"/> Female	<input type="checkbox"/> cs <input type="checkbox"/> ncs
Hematocrit	<input checked="" type="checkbox"/> Male <input type="text"/> <input type="text"/> <input type="text"/> 0 . <input type="text"/> 1 % <input type="checkbox"/> Female	<input type="checkbox"/> cs <input type="checkbox"/> ncs
Hematocrit value meets critical value level of < 15 % or > 65 %.		
MCV	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> fL	<input type="checkbox"/> cs <input type="checkbox"/> ncs
MCH	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> g/dL	<input type="checkbox"/> cs <input type="checkbox"/> ncs
MCHC	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> g/dL	<input type="checkbox"/> cs <input type="checkbox"/> ncs
RDW	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> %	<input type="checkbox"/> cs <input type="checkbox"/> ncs

TEST NAME	RESULT	RATING
Platelet (PLT)	<div> <div></div> <div></div> <div></div> <div>1</div> </div> K/uL	<input type="checkbox"/> cs <input type="checkbox"/> ncs
Platelet value meets critical value level of < 30 K/uL or > 1500 K/uL.		

Urinalysis (Macroscopic)

☐ Yes ☐ No Urinalysis (macroscopic) test results data captured.

Urinalysis test accession number was reported by Solstas Lab Partners on / /

TEST NAME	RESULT	RATING
Color	red	<input type="checkbox"/> cs <input type="checkbox"/> ncs
Appearance	cloudy	<input type="checkbox"/> cs <input type="checkbox"/> ncs
Specific Gravity	<div><div></div></div> . <div><div></div><div></div><div></div></div>	NA
pH	<div><div></div></div> . <div><div></div></div>	NA
Glucose	<div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div></div> mg/dL	<input type="checkbox"/> cs <input type="checkbox"/> ncs
Bilirubin	small (+)	<input type="checkbox"/> cs <input type="checkbox"/> ncs
Ketone	small (15) mg/dL	<input type="checkbox"/> cs <input type="checkbox"/> ncs
Blood	trace	<input type="checkbox"/> cs <input type="checkbox"/> ncs
Protein	trace mg/dL	<input type="checkbox"/> cs <input type="checkbox"/> ncs

Urinalysis (macroscopic) cont.

TEST NAME	RESULT	RATING
Urobilinogen	<div><div></div> . <div></div> mg/dL</div>	<div><div></div> cs</div> <div><div></div> ncs</div>
Nitrite	negative	<div><div></div> cs</div> <div><div></div> ncs</div>
Leukocytes	small (1+)	<div><div></div> cs</div> <div><div></div> ncs</div>

Comments:

Clinical Laboratory Test Review

By entering my username and password I am affixing my electronic signature to this form. I state that I have conducted a complete review of laboratory test results (per the protocol) for this subject and have identified and noted, to the best of my ability, any significant abnormalities that may preclude this subject from safely being discharged from the study.

Investigator Signature

16.1.3 List of Independent Ethics Committee (IEC) or Institutional Review Boards (IRBs), Sample Subject Information, and Sample Consent Form

16.1.3.1 Institutional Review Board and Sample Consent Form

Independent IRB, Inc. reviewed and approved the study protocol, informed consent form, and other required study documentation prior to study initiation. The IRB chairperson was Frances Conway, RN. Contact information for the IRB is provided below:

Independent IRB, Inc.
Sawgrass Plaza, Suite 120
1550 Sawgrass Corporate Parkway
Sunrise, Florida 33323
[Formerly located at: 6738 West Sunrise Blvd., Suite 102, Plantation, FL 33313]
Phone: 954-327-0778
Fax: 866-258-6674
Website: <http://iirb.com>
FDA/OHRP Registration #: IRB00003563
Primary Contact: Shelley Blanco (954) 327-0778

The sample informed consent form dated 03 August 2011 is provided on the following pages.

**INFORMED CONSENT AUTHORIZATION TO PARTICIPATE
IN A RESEARCH STUDY**

Protocol Number: CSD1101

Title: Assessment of Smokers' Nicotine Uptake and Urge to Smoke After Use of Smokeless Tobacco Products

Principal Investigator: Gregory P. Tarleton, PharmD, MD

Site of Investigation: Bellomy Research
4305 Enterprise Drive, Suite E
Winston-Salem, NC 27106

24-Hour Telephone #: 336-480-8321

Site Telephone #: 336-741-6877

Sponsor: R.J. Reynolds Tobacco Company

Participant's Name: _____

You are invited to participate in a research study. Before you give your consent to be a research participant, please read the following and ask as many questions as necessary to be sure that you understand the risks and what your participation will involve.

The Study is being sponsored by R.J. Reynolds Tobacco Company (RJRT). The Study Doctor is being paid by RJRT to conduct this study. However, the Study Doctor will not receive any financial benefit based on the outcome or results of this study.

This study will be performed for RJRT's research purposes.

NATURE AND PURPOSE OF THE STUDY

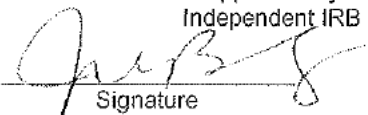
CAMEL Snus is a smokeless tobacco product that has been sold in the United States by RJRT since 2006. CAMEL Snus is in the form of pouched tobacco, which is placed in the mouth for a certain time period. (b) (4)

(b) (4)

Smokeless tobacco products are intended to be a smoke-free tobacco alternative for smokers.

The main purpose of this study is to collect biological data from cigarette smokers who will use smokeless tobacco products (1 CAMEL Snus (b) (4)) and their usual brand of cigarette during the study. These data will be obtained by analyzing samples of blood collected over three hours on five different days. In addition,

Version: 03-Aug-2011
Protocol: CSD1101

Approved By Independent IRB	
	03-Aug-2011
Signature	Date

Initials: _____

Date: _____

these data may be useful in determining levels of tobacco exposure in cigarette smokers. You will be asked questions about how you feel before and after you use each tobacco product (both the smokeless products and your usual brand cigarette).

This study is for research purposes only and is not intended to treat any medical condition.

RESEARCH PARTICIPANT SELECTION

You are being invited to participate in this research study because you are a male or female smoker who is 21-55 years of age and in generally good health. You usually smoke 10 to 30 cigarettes per day and inhale the smoke. You typically do not use other forms of tobacco. You are not putting off a decision to quit smoking to participate in this study. Research participants must also meet certain other requirements to participate in this study.

Women who are pregnant or nursing a child may not participate in this study. Women must be surgically sterile (e.g., tubal ligation, hysterectomy, etc.) for at least 90 days or agree to use a form of contraception considered acceptable to the study doctor (such as oral, injectable or implantable contraceptives, intra-uterine device and/or barrier methods) from the time of signing the informed consent through study discharge.

It is important that you answer all of the screening questions completely. You must provide information on all past and present diseases, medical conditions, allergies, and all medications that you are taking, including prescription and non-prescription medications (including dietary supplements and herbal supplements). You must be honest about your current state of health and your current tobacco use.

Up to 20 participants may be enrolled in this single-site research study.

STUDY DURATION

The length of your participation in this study will be approximately 10 weeks, including the screening visit. The study requires 5 test visits. There will be 7-18 days between these visits. A screening visit is required within 30 days of the start of the study. The Screening Visit will last about 2½ hours, and each Test Visit will last about 5 hours. If you complete all Test Visits, your participation will be over at the end of Test Visit 5.

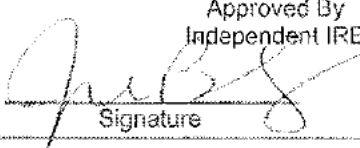
STUDY DESIGN

This study requires five separate test visits following the Screening Visit. At Test Visit 1, you will be asked to provide and smoke 1 of your usual brand cigarettes. At Test Visits 2, 3, 4 and 5, you will receive 1 of 4 different smokeless tobacco products in a random (by chance) order. By the end of the study, you will have received all 4 study products. You will not have a choice as to which product you receive at each Test Visit.

The (b) study products are as follows:

- CAMEL Snus given as a moist pouched snuff product
- (b) (4)

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(b) (4)

You will continue to smoke your usual brand of cigarette for the duration of the study. You will be given a Cigarette Use Log to record the number of cigarettes you smoke each day. You will return the completed log at each Test Visit. **You will be asked not to smoke or use any product that contains nicotine for at least 12 hours before each Test Visit.** Because no tobacco use for at least 12 hours is so important to study results, your breath will be tested for carbon monoxide levels at the start of each Test Visit. If your breath is free of carbon monoxide, you may be asked (at the discretion of the Study Doctor) to complete the Test Visit.

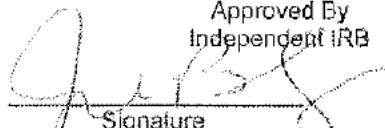
During each Test Visit, blood samples will be collected over three hours just before and several times after you use the study product. Blood will be collected through a small tube (catheter) placed in a vein in your arm or hand at each Test Visit. A short questionnaire will be given to you multiple times during each Test Visit to assess how you feel before and after using your usual brand cigarette or the smokeless tobacco product.

SCREENING

Prior to any procedures being performed, you will be asked to sign this informed consent form. During the Screening Visit, you will have the following procedures performed:

- Your demographics (for example, your age and gender) will be recorded.
- Your photo ID will be photocopied.
- Your history of tobacco use will be reviewed with you.
- Your usual brand of cigarette will be documented and photocopied.
- You will be asked to estimate the time you last smoked.
- You will be asked to breathe into a machine that will measure the level of carbon monoxide in your breath.
- Your medical and medication history will be reviewed.
- Your height and weight will be measured.
- Your blood pressure, temperature, and pulse will be measured.
- You will have a brief physical, including an exam of your mouth, performed by the Study Doctor.
- You will have a urine screening test for drugs of abuse. This test must be negative for you to continue in the study.
- If you are a female, you will have a urine pregnancy test to be sure you are not pregnant. You will also be asked whether you are currently breast feeding a baby. Your current form of birth control will be discussed and documented.
- You will provide a blood sample to be collected by needle stick. This blood sample will be tested for standard lab tests. Test results will be reviewed by the Study Doctor following your Screening Visit to determine if you are eligible to participate.
- You will also complete two short questionnaires, with six to seven questions each.

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After reviewing the results of the screening tests and other assessments, the Study Doctor will decide if you can continue in the study. You must meet all of the study conditions. You will be notified of any test results that exclude you from participating in the study.

Study staff will call to let you know whether you qualify or do not qualify for the study. If you qualify and still choose to participate, you will be scheduled for Test Visit 1. Although you may qualify, there is a chance that you will not be scheduled for the study. An example might include, but is not limited to, a conflict(s) with scheduling Test Visits.

STUDY PROCEDURES

If you are scheduled for Test Visit 1, you will:

- Record the number of cigarettes you smoke each day for seven days before Test Visit 1.
- Stop smoking and not use any products that contain nicotine for at least 12 hours before Test Visit 1.
- Return and complete additional screening procedures at check-in for Test Visit 1.

If you are not asked to continue in the study at Test Visit 1, you will be paid for your time.

If you are selected to participate at Test Visit 1, you will be asked to complete the rest of the study. You will stop smoking and will not use any product that contains nicotine for at least 12 hours before each Test Visit. You may resume smoking your usual brand cigarettes after each Test Visit.

Test Visit 1

You will arrive at the research clinic at 8:00 a.m. You will bring at least one of your usual brand cigarettes. You will also return your seven-day Cigarette Use Log.


After checking in, you will have the following procedures performed:

- Your blood pressure, temperature, and pulse will be measured.
- You will have a urine screening test for drugs of abuse. This test must be negative for you to continue in the study.
- If you are female, you will have a urine pregnancy test to be sure you are not pregnant.
- You will be asked to breathe into a machine that will measure the level of carbon monoxide (CO) in your breath. Your CO must be below a given level to be eligible to participate in the study.

After reviewing the results of the check-in tests, the Study Doctor will decide if you can be in the study. You must meet all of the study conditions.

If you qualify and you are enrolled, you will have the following procedures performed:

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- You will have a thin tube (catheter) inserted into a vein in your arm or hand. This tube will be placed using a needle like those used for a typical blood draw.
- Once in place, the tube will be capped. The tube and cap will remain in place throughout the Test Visit.
- To keep the tube from clotting, a small amount of blood thinner (approximately 0.1 ml of heparin) will be put into the cap after each blood collection.
- Before each blood collection, approximately 1 ml of fluid (containing blood and heparin) will be flushed from the cap and discarded.
- After the last blood collection, the tube and cap will be removed.
- You will smoke one of your usual brand cigarettes that you will provide to study staff upon check-in.
- You will have up to 16 tubes of blood collected during the Test Visit. Two tubes will be collected before you smoke your cigarette and the rest at specific times after you smoke.
- You will also complete a short seven-question questionnaire 10 times during the Test Visit.

At the end of Test Visit 1, you will be required to use one smokeless tobacco product to completion. Product will be provided based on a random (by chance) order. This will be the product that you will use in your next Test Visit. You will not have a choice as to which product you will receive. If you decide that you do not like the product or cannot follow the product use instructions, you may withdraw from the study.

Test Visits 2, 3, 4 and 5

You will arrive at the research clinic at 8:30 a.m. You will return your completed seven-day Cigarette Use Log.

After checking in, you will have the following procedures performed:

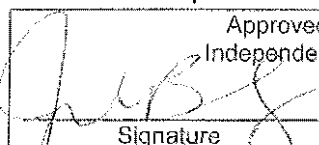
- Your blood pressure will be measured.
- If you are female, you will have a urine pregnancy test to be sure you are not pregnant.
- You will have the carbon monoxide (CO) level in your breath measured. Your CO must be below a given level to be allowed to complete the Test Visit procedures for that day.
- **If your CO is high once during the study**, you will have one chance to make up a Test Visit.
- **If your CO is high twice during the study**, you will not be allowed to continue in the study. You will be dismissed from the study.

If you pass all check-in procedures, you will have the following procedures performed:

- You will have a thin tube (catheter) inserted into a vein in your arm or hand. This tube will be placed using a needle like those used for a typical blood draw.
- Once in place, the tube will be capped. The tube and cap will remain in place throughout the Test Visit.
- To keep the tube from clotting, a small amount of blood thinner (0.1 ml of heparin) will be put into the cap after each blood collection.

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- Before each blood collection, approximately 1 ml of fluid (containing blood and heparin) will be flushed from the cap and discarded.
- After the last blood collection, the tube and cap will be removed.
- You will use one unit of a smokeless tobacco product according to instructions at each Test Visit.

Depending on the product, you will be asked to place the product:

- Between your upper or lower lip and gum *or*,
- Between your cheek and gum *or*,
- Under your tongue.
- You will also be asked to occasionally move the product to a different place in your mouth.

Depending on the product, you will use the product until it is gone or between 15 and 30 minutes.

While using the product you will **not** be allowed to:

- Eat or drink,
- Chew the product,
- Spit during or after use (during test visit),
- Swallow the product, or Smoke.
- You will have up to 16 tubes of blood collected during each Test Visit. Two tubes will be collected before you use the study product and the rest at specific times while/after you use the product.
- You will also complete a short seven-question questionnaire 10 times during each Test Visit.


At the end of Test Visits 2, 3 and 4, you will be required to use one smokeless tobacco product to completion. Product will be provided based on a random (by chance) order. This will be the product that you will use in your next Test Visit. You will not have a choice as to which product you will receive. If you decide that you do not like the product or cannot follow the product use instructions, you may withdraw from the study.

At the end of Test Visit 5, you will have the following procedures performed:

- You will have two additional tubes of blood collected (approximately 10 ml) from the tube (catheter) in your arm or hand to re-check standard lab tests.
- You will provide a urine sample for a final urinalysis (standard lab tests).
- Your pulse will be measured.
- You will have a physical exam, including an exam of your mouth, performed by the Study Doctor.
- You will complete an exit questionnaire that will ask you questions about your study experience.

At Test Visit 5, after adequate evaluation by the study staff and with permission of the Study Doctor, you will be discharged from the research clinic, and your participation in

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this study will be complete.

If necessary, the Study Doctor may require that you stay longer for observation in the research clinic.

Blood Sampling

Blood samples will be taken approximately 81 times during the study. Approximately 390 ml of blood (about 13.2 fluid ounces or about 1.6 cups) will be drawn during the study. For comparison, a standard blood donation at a blood collection center is about 500 ml (approximately 2 cups) of blood. Additional blood samples may be required if any of your lab values are abnormal. It is possible that more than one attempt to obtain a blood sample may be necessary.

Restrictions and Research Participant Responsibilities

As a research participant, you will be asked to complete the following study procedures:

- You will come to the research clinic on time for all of your scheduled visits.
- You will follow the instructions listed in this informed consent form and explained to you by study staff.
- You will notify the Study Doctor or study staff if any information regarding your health or availability to participate in this study changes.
- You will smoke only your usual brand cigarettes throughout the study.
- You will not use any product that contains nicotine for at least 12 hours before each Test Visit.
- You will not eat or drink while using product during your Test Visits.
- You will record your daily cigarette use on the seven-day Cigarette Use Log prior to each Test Visit throughout the study. You will return the completed log at each Test Visit.
- You will not make blood donations while taking part in this study.
- For all females, you must have negative urine pregnancy test results at Screening and at all Test Visits to participate. You will use an acceptable form of birth control throughout the study.

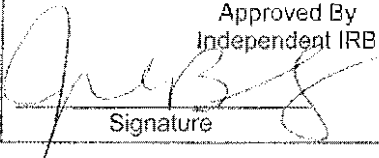
RISKS AND DISCOMFORTS

There may be risks to you if you participate in this study. As a cigarette smoker, the risks associated with smoking will remain the same. According to the Surgeon General and other public health authorities, all tobacco products carry significant risks.

Tobacco-burning cigarettes have been required by law to carry one of the four following warnings:

- SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, and May Complicate Pregnancy.
- SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health.
- SURGEON GENERAL'S WARNING: Smoking by Pregnant Women May Result

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in Fetal Injury, Premature Birth, and Low Birth Weight.

- SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide.

Starting in 2012, cigarettes will be required by law to carry the following warnings:

- WARNING: Cigarettes are addictive.
- WARNING: Tobacco smoke can harm your children.
- WARNING: Cigarettes cause fatal lung disease.
- WARNING: Cigarettes cause cancer.
- WARNING: Cigarettes cause strokes and heart disease.
- WARNING: Smoking during pregnancy can harm your baby.
- WARNING: Smoking can kill you.
- WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.
- WARNING: Quitting smoking now greatly reduces serious risks to your health.

As of 2010, smokeless tobacco products are required by law to carry the following warnings:

- WARNING: This product can cause mouth cancer.
- WARNING: This product can cause gum disease and tooth loss.
- WARNING: This product is not a safe alternative to cigarettes.
- WARNING: Smokeless tobacco is addictive.

The smokeless tobacco products used in this study are not intended to cause side effects. However, in previous studies that have tested smokeless tobacco products, some participants have reported the following symptoms:

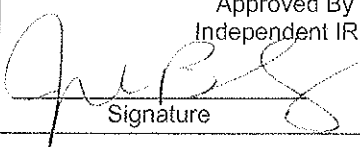
- Indigestion/Heartburn/Upset Stomach
- Nausea
- Mouth Tingle/Burn/Irritation
- Throat Discomfort/Burn/Irritation
- Gum/Cheek Numbness/Tingle
- Increased Burping
- Dry Mouth
- Tooth/Gum Sensitivity
- Headache
- Dizziness
- Hiccups

STUDY PROCEDURE RISKS

Blood Samples

There may be discomfort when the catheter is placed and withdrawn. As with any needle stick, there is a risk of infection, bruising, and bleeding. Sterile procedures will be used to limit the risk of infection. Lightheadedness and/or fainting may also occur during or after catheter placement as well as during blood sample collections.

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If a study staff member is exposed to your blood, you agree to have another blood sample drawn for testing purposes. This additional sample will be tested for hepatitis and HIV. If this is required, you will be called back to the research clinic to provide the blood sample. You and the exposed staff member will be notified of any test results.

Expired Carbon Monoxide (ECO)

This procedure measures the amount of carbon monoxide in your breath. Carbon monoxide is inhaled from smoking and can be taken in from other sources. To complete the procedure, you will be asked to take a deep breath and hold it for 15 seconds. You will then exhale slowly until your lungs feel completely empty.

Because the ECO test is a non-invasive procedure, it is safe and painless for most individuals. However, possible side effects may include:

- Dizziness or light-headedness,
- Coughing.

Completion of Questionnaires

There are no known risks associated with completing the questionnaires in this study. Completion of the questionnaires is required as part of your study participation.

UNKNOWN/UNFORESEEABLE RISKS

In addition to the risks listed above, there may be other unknown, infrequent, or unforeseeable risks associated with the use of tobacco products.

You will be informed in a timely manner (both verbally and in writing) of any new information, findings, or changes to the way the research will be performed that might influence your willingness to continue your participation in this study.

PREGNANCY RISKS

The Surgeon General warns that cigarette smoking by pregnant women may harm the unborn baby, complicate pregnancy, and may result in premature birth and low birth weight. Women who are pregnant or planning to become pregnant, or who are breast feeding cannot participate in this study.

BENEFITS

You understand that your participation in this study is purely for RJRT's research purposes and no benefits to you are expected or promised.


COST

You will be asked to purchase your usual brand of cigarettes for use in this study. Your usual brand cigarettes will not be paid for or provided by the research clinic or Sponsor. There are no other costs to you for participating in this research study. The study Sponsor will pay for all other study costs.

PAYMENT

You may be paid up to \$1,615.00 for the time and travel required to complete the

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Screening Visit and five Test Visits. You will be paid \$95 for the Screening Visit. Selected study participants will be paid \$290.00 per visit for completing Test Visits 1, 2, 3, and 4, and \$310.00 for completing Test Visit 5. Those who are not asked to become participants will be paid \$50 for the time and travel required to report for Test Visit 1. Those who do not qualify at Test Visit 1 will be compensated \$50 for the time and travel required to attend Test Visit 1 **only**. If you do not complete the entire study, you will be paid only for the visits you complete based on the following payment schedule:

Payment Breakdown	Eligible Study Participants	Did <u>not</u> complete Test Visit 1
Screening Visit	\$95.00	\$95.00
Test Visit 1	\$290.00	\$50.00
Test Visit 2	\$290.00	N/A
Test Visit 3	\$290.00	N/A
Test Visit 4	\$290.00	N/A
Test Visit 5	\$310.00	N/A
Non-Qualifying Test Visit ¹	\$50.00	N/A
Total	\$1615.00	\$145.00

¹If you do not pass the expired CO inclusion criteria at any single Test Visit after Test Visit 1, you will be allowed one make-up visit. If you fail the ECO a second time, you will be dismissed from the study.

A payment of \$20.00 (for time and travel) will apply if you attend the Screening Visit and decide you are not interested in participating in the study, prior to signing the informed consent form.

ALTERNATIVE

Since this study is not intended to provide participants any therapeutic or other health-related benefit, you have the option to not participate in this study.

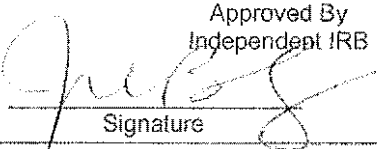
RIGHT TO WITHDRAW OR REMOVAL FROM STUDY

Participation in this research study is voluntary. You are free to withdraw from this study at any time for any reason. You agree to inform the study staff immediately if you intend to withdraw but you do not have to state your reason. If you withdraw because you intend to quit using tobacco, the Study Doctor will refer you to appropriate resources to help you stop smoking or using tobacco.

To terminate your participation in this study, you must contact the study staff at the 24-hour telephone number listed on Page 1 of this informed consent form. Your decision to participate in this study or to withdraw from this study will not influence the availability of your future medical care and will involve no penalty or loss of benefits to which you are otherwise entitled.

You understand that the Study Doctor can remove you from this study without your consent for any reason, including, but not limited to:

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- a. A change in your qualification status that makes you no longer eligible for participation according to the study requirements or which may affect your safety.
- b. Your failure to follow the instructions of the Study Doctor or study staff.
- c. If the study is stopped by the Sponsor and/or the Study Doctor prior to its completion.

Should you decide to withdraw from participation in the study or if the Study Doctor decides to remove you from the study for any reason, you will be asked to complete the following final safety procedures: a brief physical, an exam of your mouth, provide blood samples for standard lab test (two tubes), and provide a urine sample for a final urinalysis.

OFFER TO ANSWER ANY QUESTIONS ABOUT THIS STUDY

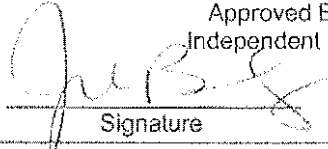
If you have any questions, concerns, or complaints during this study, or if you think you may have experienced a research-related injury, you should call the 24-hour telephone number (336) 480-8321.

If you have any questions regarding your rights as a research participant, please contact the Independent Investigational Review Board, Inc. at toll free 1-(877) 888-iiirb (4472) during regular working hours. You can also contact the Independent Investigational Review Board, Inc. if you would like to report problems in a research study, express concerns, ask questions, request information, or provide input. The Independent Investigational Review Board is a committee established for the purpose of protecting the rights of participants in a research study. For more information about your rights and role as a research participant you can visit the Research Participant section of the IIRB, Inc. website at www.iiirb.com.

USE AND DISCLOSURE OF MEDICAL INFORMATION

As part of this study, the Study Doctor and study staff at the research clinic will keep records of your participation in the study. These study records will include personal information that you provide including your age, gender, medical history, the results of procedures and tests you undergo during the study or as part of the screening for the study, information about your responses while participating in the study, and other medical information related to your participation in the study. By participating in this research study, your records become part of the research records. Under federal law your study records cannot be used or disclosed by the research clinic for research purposes unless you authorize the release of those records by signing this informed consent form. You may not participate in the study unless you sign this informed consent form. If you sign this informed consent form, you will be agreeing to the disclosures of your personal information to certain third parties discussed below. While these third parties will have full access to the test results and information resulting from this study, your study records will be assigned a code number by the study team, so that you will not be identified by name or other unique identifying information (such as Social Security Number) in any records sent to the third parties. The list that matches your name with the code number will be kept in a locked file at the research clinic.

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Your study results may be disclosed to the following third parties:

- (i) the Sponsor of this study, R.J. Reynolds Tobacco Company, its employees and its contractors, including select employees and contractors who will be involved in the conduct of the study under supervision of the Study Doctor;
- (ii) the Food and Drug Administration ("FDA"), the Department of Health and Human Services ("DHHS"), the Office of Human Research Protections ("OHRP"), the Office of Civil Rights ("OCR") and other U.S. and foreign governmental and/or regulatory agencies; and
- (iii) the Independent Investigational Review Board, Inc., an ethics committee that reviews the conduct of human research studies.

In addition, your personal information may be disclosed, without prior notice to you, in response to a valid court order by a court or other governmental or regulatory body or as otherwise required by law.

The Sponsor, the research clinic, and the Independent Investigational Review Board, Inc., will take reasonable efforts, consistent with industry standards, to protect the confidentiality and security of your personal information during and after this study. No publication about the research will reveal your identity or personally identifiable information. These limitations continue even if you revoke this authorization.

Because of the need to release information to the Sponsor, the Independent Investigational Review Board, Inc., and relevant governmental and/or regulatory agencies, absolute confidentiality cannot be guaranteed. However, the Sponsor and its designees will use your information only for purposes of this study and will not disclose your study records to any non-governmental third parties unless required by law.

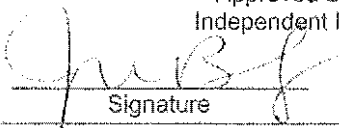
Your study records may be kept by the research clinic for a specific period of time as required by law following the completion of the study. The data generated by the study, including data collected from you, will become the exclusive property of the Sponsor (RJRT), and you will have no rights to any inventions, products, or intellectual property developed using your data. While the research is in progress, you will not have the right to review or copy your study records. However, you will be allowed to see that information when the entire research project has been completed.

This authorization to use and disclose your medical information has no expiration date. However, as noted above, you have the right to withdraw this authorization at any time by giving written notice to the study doctor at the address listed on page 1 of this form. If you withdraw from the study, the information that has already been collected in your study record may continue to be used and disclosed as described above; however, no new information will be obtained or added.

IN CASE OF INJURY

If during the course of this study, any injury occurs to you as a direct result of performed study procedures, the study Sponsor, R.J. Reynolds Tobacco Company, agrees to pay all medical expenses necessary to treat such injury (1) to the extent you are not

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otherwise reimbursed by medical insurance and (2) provided you have followed the directions of the Study Doctor and study staff.

Financial compensation for things such as lost wages, disability or discomfort due to injury will not be covered.

You **DO NOT** waive any of your legal rights as a research participant by signing this consent form.

CLOSING STATEMENT

You have read the statements in this informed consent document. You have received satisfactory answers to all of the questions that you have asked and you willingly signed and initialed each page of this consent form. You will receive a copy of the signed informed consent. You hereby consent to be a participant in this study.

SIGNATURES

I have read the above information in a language that I understand well. The content and meaning of this information has been explained to me. I hereby voluntarily consent and offer to take part in this study and authorize the use and disclosure of my medical information as described in this document.

<u>Print Research Participant Name</u>	<u>Research Participant Signature</u>	<u>Date/Time (HH:MM:SS)</u>
--	---------------------------------------	-----------------------------

<u>Print Name of Person conducting the Informed Consent discussion</u>	<u>Signature of Person conducting the Informed Consent discussion</u>	<u>Date/Time (HH:MM:SS)</u>
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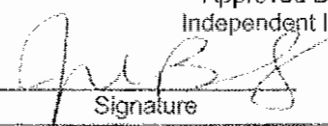
<u>Print Name of Investigator</u>	<u>Signature of Investigator</u>	<u>Date/Time (HH:MM:SS)</u>
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Copy of consent form given to research participant:

By (initials) _____ on (date) _____

Independent Investigational Review Board, Inc.
Approved: 7/26/2011 Revised: 8/3/2011

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Approved By Independent IRB	
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Signature	Date

Initials: _____

Date: _____

16.1.3.2 Representative Written Subject Information

Copies of the [Fagerström Test for Nicotine Dependence](#), [Mood and Physical Symptoms Scale](#), [Exit Questionnaire](#), and [Cigarette Use Logs](#) (for recording of at-home UB cigarette use) are provided on the following pages.

Subjects were provided with a study contact card (shown below), and [calendars](#) (provided on the following pages).

Study Contact Information

**If you have any questions regarding scheduling,
study-related medical concerns, study
instructions, product, and/or supplies,**

Call the 24-hour study #: 336-480-8321

Subject Initials: _____
Screening No. : _____
Randomization No. : _____
Visit No. : _____
Date: _____
Time Issued : _____

The Fagerström Test for Nicotine Dependence

1. How soon after you wake up do you smoke your first cigarette?

Within 5 minutes _____ (3)
6 - 30 minutes _____ (2)
31- 60 minutes _____ (1)
After 60 minutes _____ (0)

2. Do you find it difficult to refrain from smoking in places where it is forbidden e.g. in church, at the library, in cinema, etc.?

Yes _____ (1)
No _____ (0)

3. Which cigarette would you hate most to give up?

The first one in the morning _____ (1)
Any other.. _____ (0)

4. How many cigarettes per day do you smoke?

≤ 10. _____ (0)
11-20 _____ (1)
21-30 _____ (2)
≥ 31. _____ (3)

5. Do you smoke more frequently during the first hours after waking than during the rest of the day?

Yes _____ (1)
No _____ (0)

6. Do you smoke if you are so ill that you are in bed most of the day?

Yes _____ (1)
No _____ (0)

Subject Initials: _____ Date: _____
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Reproduced with permission.

Source: Heatherton, T. F., L. T. Kozlowski, et al. (1991). "The Fagerström Test for Nicotine Dependence: a revision of the Fagerström Tolerance Questionnaire." Br J Addict **86**(9): 1119-27

Subject Initials: _____
Screening No. : _____
Randomization No. : _____
Visit No. : _____
Date: _____
Time Point : _____
Time Issued : _____

Mood and Physical Symptoms Scale

Please show for each of the items below how you currently feel.
(Circle one number for each item.)

	Not at all	Slightly	Somewhat	Very	Extremely
1. Depressed	1	2	3	4	5
2. Anxious	1	2	3	4	5
3. Irritable	1	2	3	4	5
4. Restless	1	2	3	4	5
5. Hungry	1	2	3	4	5
6. Poor concentration	1	2	3	4	5

7. How strong is your current urge to smoke? (Circle one number.)

No urges	Slight	Moderate	Strong	Very strong	Extremely strong
0	1	2	3	4	5

Reproduced with permission.

Source: West R and Hajek P. 2004. Evaluation of the mood and physical symptoms scale (MPSS) to assess cigarette withdrawal.
Psychopharmacology 177:195-199.

Subject Initials: _____
Date: _____

Exit Questionnaire

Your opinion counts! Please give us your input about the study you are completing. Answer each question by circling the number corresponding to the best answer. Circle only one choice unless indicated otherwise. When completed, please return your questionnaire to a study staff member.

- 1) Below is a list of activities that were required of you during the course of the study. On a scale of 1 to 7, with 1 being “Extremely Unappealing,” 4 being neither “Neither Appealing nor Unappealing” and 7 being “Extremely Appealing,” how appealing was each of the following activities to you? (Circle one rating for each item.)

	(Circle one rating for each)						
	Extremely Unappealing			Neither Appealing nor Unappealing			Extremely Appealing
Visits every week	1	2	3	4	5	6	7
Travel to and from the site	1	2	3	4	5	6	7
Compensation	1	2	3	4	5	6	7
Length of the study	1	2	3	4	5	6	7
Products you were asked to use	1	2	3	4	5	6	7
Completing questionnaires	1	2	3	4	5	6	7
12-hour smoking abstinence	1	2	3	4	5	6	7
Catheter insertion	1	2	3	4	5	6	7
Blood collection	1	2	3	4	5	6	7
3-4 hour study visits	1	2	3	4	5	6	7

- 2) How would you rate each of the following characteristics of the study? (Circle one rating for each item.)

	(Circle one rating for each)				
	Poor	Fair	Good	Very Good	Excellent
Convenience of the site location	1	2	3	4	5
Cleanliness of the facilities	1	2	3	4	5
Comfort of the site	1	2	3	4	5
Comfort with the nurses	1	2	3	4	5
Comfort with other study team members	1	2	3	4	5
Encouragement and motivation by the study team members in helping me achieve my study goals	1	2	3	4	5

- 3) Why or why not would you consider participating in a similar study in the future?
(Please be as specific as possible.)

- 4) Did you enjoy participating in this study? Why or why not? (Please be as specific as possible.)

- 5) Do you have any additional comments or suggestions that you would like to share with us? (Please be as specific as possible.)

Subject Initials _____
Screening No. _____
Subject No. _____
Test Visit _____

CIGARETTE USE LOG

PLEASE RECORD THE NUMBER OF **CIGARETTES** YOU SMOKE PER DAY FOR THE
NEXT **SEVEN** DAYS.

****Remember, you are allowed to smoke ONLY your Usual Brand
cigarettes until the completion of this study.****

Day 1: Date: ____/____/____ Number of **cigarettes** smoked today _____
(Day) (Month) (Year)

Day 2: Date: ____/____/____ Number of **cigarettes** smoked today _____
(Day) (Month) (Year)

Day 3: Date: ____/____/____ Number of **cigarettes** smoked today _____
(Day) (Month) (Year)

Day 4: Date: ____/____/____ Number of **cigarettes** smoked today _____
(Day) (Month) (Year)

Day 5: Date: ____/____/____ Number of **cigarettes** smoked today _____
(Day) (Month) (Year)

Day 6: Date: ____/____/____ Number of **cigarettes** smoked today _____
(Day) (Month) (Year)

Day 7: Date: ____/____/____ Number of **cigarettes** smoked today _____
(Day) (Month) (Year)

• Do **NOT** smoke after 8:00 p.m. on Day 7.

• Time last smoked on Day 7: _____:

Comments/Observations:

Subject Initials: _____ Date: _____

(Staff only) Reviewed By: _____ Date: _____

Subject Initials _____
Screening No. _____
Randomization No. _____
Test Visit _____

CIGARETTE USE LOG (Cont.)

PLEASE RECORD THE NUMBER OF CIGARETTES YOU SMOKE PER DAY.

****Remember, you are allowed to smoke ONLY your Usual Brand cigarettes until the completion of this study.****

Day 8: Date: ____/____/____ **Number of cigarettes smoked today** ____
(Day) (Month) (Year)

Day 9: Date: ____/____/____ **Number of cigarettes smoked today** ____
(Day) (Month) (Year)

Day 10: Date: ____/____/____ **Number of cigarettes smoked today** ____
(Day) (Month) (Year)

Day 11: Date: ____/____/____ **Number of cigarettes smoked today** ____
(Day) (Month) (Year)

Day 12: Date: ____/____/____ **Number of cigarettes smoked today** ____
(Day) (Month) (Year)

Day 13: Date: ____/____/____ **Number of cigarettes smoked today** ____
(Day) (Month) (Year)

Day 14: Date: ____/____/____ **Number of cigarettes smoked today** ____
(Day) (Month) (Year)

Day 15: Date: ____/____/____ **Number of cigarettes smoked today** ____
(Day) (Month) (Year)

Day 16: Date: ____/____/____ **Number of cigarettes smoked today** ____
(Day) (Month) (Year)

Day 17: Date: ____/____/____ **Number of cigarettes smoked today** ____
(Day) (Month) (Year)

Day 18: Date: ____/____/____ **Number of cigarettes smoked today** ____
(Day) (Month) (Year)

• **Do NOT smoke after 8:00 p.m. on the day prior to test visit.**

• **Time last smoked on Day ____: ____:**

Subject Initials: _____ **Date:** _____

(Staff only) Reviewed By: _____ **Date:** _____

October/November 2011

Monday Test Visits

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
October 23	October 24 <i>Record # cigarettes smoked</i> <i>Log Sheet – Day 1</i>	October 25 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 2</i>	October 26 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 3</i>	October 27 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 4</i>	October 28 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 5</i>	October 29 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 6</i>
October 30 <i>Record # of cigarettes smoked.</i> No smoking after 8:00 p.m. <i>Log Sheet – Day 7</i>	October 31 <i>Report to Bellomy at 8:00 a.m. with completed log sheet (Test Visit 1)</i> <i>Record # cigarettes smoked</i> <i>Log Sheet – Day 1</i>	November 1 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 2</i>	November 2 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 3</i>	November 3 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 4</i>	November 4 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 5</i>	November 5 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 6</i>
November 6 <i>Record # of cigarettes smoked.</i> No smoking after 8:00 p.m. <i>Log Sheet – Day 7</i>	November 7 <i>Report to Bellomy at 8:30 a.m. with completed log sheet (Test Visit 2)</i> <i>Record # cigarettes smoked</i> <i>Log Sheet – Day 1</i>	November 8 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 2</i>	November 9 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 3</i>	November 10 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 4</i>	November 11 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 5</i>	November 12 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 6</i>
November 13 <i>Record # of cigarettes smoked.</i> No smoking after 8:00 p.m. <i>Log Sheet – Day 7</i>	November 14 <i>Report to Bellomy at 8:30 a.m. with completed log sheet (Test Visit 3)</i> <i>Record # cigarettes smoked</i> <i>Log Sheet – Day 1</i>	November 15 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 2</i>	November 16 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 3</i>	November 17 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 4</i>	November 18 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 5</i>	November 19 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 6</i>

November/December 2011

Monday Test Visits

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
November 20 <i>Record # of cigarettes smoked</i> <i>Log Sheet - Day 7</i>	November 21 <i>Record # of cigarettes smoked</i> NO TEST VISIT THIS WEEK <i>Log Sheet - Day 8</i>	November 22 <i>Record # of cigarettes smoked</i> <i>Log Sheet - Day 9</i>	November 23 <i>Record # of cigarettes smoked</i> <i>Log Sheet - Day 10</i>	November 24 <i>Record # of cigarettes smoked</i> <i>Log Sheet - Day 11</i>	November 25 <i>Record # of cigarettes smoked</i> <i>Log Sheet - Day 12</i>	November 26 <i>Record # of cigarettes smoked</i> <i>Log Sheet - Day 13</i>
November 27 <i>Record # of cigarettes smoked.</i> No smoking after 8:00 p.m. <i>Log Sheet - Day 14</i>	November 28 <i>Report to Bellomy at 8:30 a.m. with completed log sheet (Test Visit 4)</i> <i>Record # cigarettes smoked</i> <i>Log Sheet - Day 1</i>	November 29 <i>Record # of cigarettes smoked</i> <i>Log Sheet - Day 2</i>	November 30 <i>Record # of cigarettes smoked</i> <i>Log Sheet - Day 3</i>	December 1 <i>Record # of cigarettes smoked</i> <i>Log Sheet - Day 4</i>	December 2 <i>Record # of cigarettes smoked</i> <i>Log Sheet - Day 5</i>	December 3 <i>Record # of cigarettes smoked</i> <i>Log Sheet - Day 6</i>
December 4 <i>Record # of cigarettes smoked.</i> No smoking after 8:00 p.m. <i>Log Sheet - Day 7</i>	December 5 <i>Report to Bellomy at 8:30 a.m. with completed log sheet (Test Visit 5)</i> <i>Record # cigarettes smoked</i> <i>Log Sheet - Day 1</i>	December 6 <i>Record # of cigarettes smoked</i> <i>Log Sheet - Day 2</i>	December 7 <i>Record # of cigarettes smoked</i> <i>Log Sheet - Day 3</i>	December 8 <i>Record # of cigarettes smoked</i> <i>Log Sheet - Day 4</i>	December 9 <i>Record # of cigarettes smoked</i> <i>Log Sheet - Day 5</i>	December 10 <i>Record # of cigarettes smoked</i> <i>Log Sheet - Day 6</i>

Study Contact Information:

If you have any questions regarding scheduling, study related medical concerns, study instructions, product and/or supplies, please call the 24-hour study # at **336-480-8321**.

December 2011

Monday Test Visits

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
December 11 <i>Record # of cigarettes smoked.</i> No smoking after 8:00 p.m. <i>Log Sheet – Day 7</i>	December 12 <i>Report to Bellomy at 8:30 a.m. with completed log sheet (Make-up Visit)</i>	December 13	December 14	December 15	December 16	December 17

Study Contact Information:

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October/November 2011

Tuesday Test Visits

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
October 23	October 24	October 25 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 1</i>	October 26 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 2</i>	October 27 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 3</i>	October 28 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 4</i>	October 29 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 5</i>
October 30 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 6</i>	October 31 <i>Record # of cigarettes smoked.</i> No smoking after 8:00 p.m. <i>Log Sheet – Day 7</i>	November 1 <i>Report to Bellomy at 8:00 a.m. with completed log sheet (Test Visit 1)</i> <i>Record # cigarettes smoked</i> <i>Log Sheet – Day 1</i>	November 2 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 2</i>	November 3 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 3</i>	November 4 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 4</i>	November 5 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 5</i>
November 6 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 6</i>	November 7 <i>Record # of cigarettes smoked.</i> No smoking after 8:00 p.m. <i>Log Sheet – Day 7</i>	November 8 <i>Report to Bellomy at 8:30 a.m. with completed log sheet (Test Visit 2)</i> <i>Record # cigarettes smoked</i> <i>Log Sheet – Day 1</i>	November 9 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 2</i>	November 10 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 3</i>	November 11 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 4</i>	November 12 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 5</i>
November 13 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 6</i>	November 14 <i>Record # of cigarettes smoked.</i> No smoking after 8:00 p.m. <i>Log Sheet – Day 7</i>	November 15 <i>Report to Bellomy at 8:30 a.m. with completed log sheet (Test Visit 3)</i> <i>Record # cigarettes smoked</i> <i>Log Sheet – Day 1</i>	November 16 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 2</i>	November 17 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 3</i>	November 18 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 4</i>	November 19 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 5</i>

November/December 2011

Tuesday Test Visits

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
November 20 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 6</i>	November 21 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 7</i>	November 22 <i>Record # of cigarettes smoked</i> NO TEST VISIT THIS WEEK <i>Log Sheet – Day 8</i>	November 23 <i>Record # of cigarettes smoked</i> <i>Log Sheet - Day 9</i>	November 24 <i>Record # of cigarettes smoked</i> <i>Log Sheet - Day 10</i>	November 25 <i>Record # of cigarettes smoked</i> <i>Log Sheet - Day11</i>	November 26 <i>Record # of cigarettes smoked</i> <i>Log Sheet - Day12</i>
November 27 <i>Record # of cigarettes smoked</i> <i>Log Sheet - Day 13</i>	November 28 <i>Record # of cigarettes smoked.</i> No smoking after 8:00 p.m. <i>Log Sheet - Day 14</i>	November 29 <i>Report to Bellomy at 8:30 a.m. with completed log sheet (Test Visit 4)</i> <i>Record # cigarettes smoked</i> <i>Log Sheet – Day 1</i>	November 30 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 2</i>	December 1 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 3</i>	December 2 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 4</i>	December 3 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 5</i>
December 4 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 6</i>	December 5 <i>Record # of cigarettes smoked.</i> No smoking after 8:00 p.m. <i>Log Sheet – Day 7</i>	December 6 <i>Report to Bellomy at 8:30 a.m. with completed log sheet (Test Visit 5)</i> <i>Record # cigarettes smoked</i> <i>Log Sheet – Day 1</i>	December 7 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 2</i>	December 8 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 3</i>	December 9 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 4</i>	December 10 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 5</i>

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December 2011

Tuesday Test Visits

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
December 11 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 6</i>	December 12 <i>Record # of cigarettes smoked.</i> No smoking after 8:00 p.m. <i>Log Sheet – Day 7</i>	December 13 <i>Report to Bellomy at 8:30 a.m. with completed log sheet (Make-up Visit)</i>	December 14	December 15	December 16	December 17

Study Contact Information:

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October/November 2011

Wednesday Test

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
October 23	October 24	October 25	October 26 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 1</i>	October 27 <i>Record # of cigarettes smoked</i> <i>Log Sheet - Day 2</i>	October 28 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 3</i>	October 29 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 4</i>
October 30 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 5</i>	October 31 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 6</i>	November 1 <i>Record # of cigarettes smoked.</i> No smoking after 8:00 p.m. <i>Log Sheet – Day 7</i>	November 2 <i>Report to Bellomy at 8:00 a.m. with completed log sheet (Test Visit 1)</i> <i>Record # cigarettes smoked</i> <i>Log Sheet – Day 1</i>	November 3 <i>Record # of cigarettes smoked</i> <i>Log Sheet - Day2</i>	November 4 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 3</i>	November 5 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 4</i>
November 6 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 5</i>	November 7 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 6</i>	November 8 <i>Record # of cigarettes smoked.</i> No smoking after 8:00 p.m. <i>Log Sheet – Day 7</i>	November 9 <i>Report to Bellomy at 8:30 a.m. with completed log sheet (Test Visit 2)</i> <i>Record # cigarettes smoked</i> <i>Log Sheet – Day 1</i>	November 10 <i>Record # of cigarettes smoked</i> <i>Log Sheet - Day 2</i>	November 11 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 3</i>	November 12 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 4</i>
November 13 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 5</i>	November 14 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 6</i>	November 15 <i>Record # of cigarettes smoked.</i> No smoking after 8:00 p.m. <i>Log Sheet – Day 7</i>	November 16 <i>Report to Bellomy at 8:30 a.m. with completed log sheet (Test Visit 3)</i> <i>Record # cigarettes smoked</i> <i>Log Sheet – Day 1</i>	November 17 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 2</i>	November 18 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 3</i>	November 19 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 4</i>

November/December 2011

Wednesday Test

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
November 20 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 5</i>	November 21 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 6</i>	November 22 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 7</i>	November 23 <i>Record # of cigarettes smoked</i> NO TEST VISIT THIS WEEK <i>Log Sheet – Day 8</i>	November 24 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 9</i>	November 25 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 10</i>	November 26 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 11</i>
November 27 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 12</i>	November 28 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 13</i>	November 29 <i>Record # of cigarettes smoked.</i> No smoking after 8:00 p.m. <i>Log Sheet – Day 14</i>	November 30 Report to Bellomy at 8:30 a.m. with completed log sheet (Test Visit 4) <i>Record # cigarettes smoked</i> <i>Log Sheet – Day 1</i>	December 1 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 2</i>	December 2 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 3</i>	December 3 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 4</i>
December 4 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 5</i>	December 5 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 6</i>	December 6 <i>Record # of cigarettes smoked.</i> No smoking after 8:00 p.m. <i>Log Sheet – Day 7</i>	December 7 Report to Bellomy at 8:30 a.m. with completed log sheet (Test Visit 5) <i>Record # cigarettes smoked</i> <i>Log Sheet – Day 1</i>	December 8 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 2</i>	December 9 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 3</i>	December 10 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 4</i>

Study Contact Information:

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December 2011

Wednesday Test

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
December 11 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 5</i>	December 12 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 6</i>	December 13 <i>Record # of cigarettes smoked.</i> No smoking after 8:00 p.m. <i>Log Sheet – Day 7</i>	December 14 <i>Report to Bellomy at 8:30 a.m. with completed log sheet (Make-up Visit)</i>	December 15	December 16	December 17

Study Contact Information:

If you have any questions regarding scheduling, study related medical concerns, study instructions, product and/or supplies, please call the 24-hour study # at **336-480-8321**.

October/November 2011

Thursday Test

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
October 23	October 24	October 25	October 26	October 27 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 1</i>	October 28 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 2</i>	October 29 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 3</i>
October 30 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 4</i>	October 31 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 5</i>	November 1 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 6</i>	November 2 <i>Record # of cigarettes smoked.</i> No smoking after 8:00 p.m. <i>Log Sheet – Day 7</i>	November 3 Report to Bellomy at 8:00 a.m. with completed log sheet (Test Visit 1) <i>Record # cigarettes smoked</i> <i>Log Sheet – Day 1</i>	November 4 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 2</i>	November 5 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 3</i>
November 6 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 4</i>	November 7 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 5</i>	November 8 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 6</i>	November 9 <i>Record # of cigarettes smoked.</i> No smoking after 8:00 p.m. <i>Log Sheet – Day 7</i>	November 10 Report to Bellomy at 8:30 a.m. with completed log sheet (Test Visit 2) <i>Record # cigarettes smoked</i> <i>Log Sheet – Day 1</i>	November 11 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 2</i>	November 12 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 3</i>
November 13 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 4</i>	November 14 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 5</i>	November 15 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 6</i>	November 16 <i>Record # of cigarettes smoked.</i> No smoking after 8:00 p.m. <i>Log Sheet – Day 7</i>	November 17 Report to Bellomy at 8:30 a.m. with completed log sheet (Test Visit 3) <i>Record # cigarettes smoked</i> <i>Log Sheet – Day 1</i>	November 18 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 2</i>	November 19 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 3</i>

November/December 2011

Thursday Test

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
November 20 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 4</i>	November 21 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 5</i>	November 22 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 6</i>	November 23 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 7</i>	November 24 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 8</i>	November 25 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 9</i>	November 26 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 10</i>
November 27 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 11</i>	November 28 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 12</i>	November 29 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 13</i>	November 30 <i>Record # of cigarettes smoked.</i> No smoking after 8:00 p.m. <i>Log Sheet – Day 14</i>	December 1 <i>Report to Bellomy at 8:30 a.m. with completed log sheet (Test Visit 4)</i> <i>Record # cigarettes smoked</i> <i>Log Sheet – Day 1</i>	December 2 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 2</i>	December 3 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 3</i>
December 4 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 4</i>	December 5 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 5</i>	December 6 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 6</i>	December 7 <i>Record # of cigarettes smoked.</i> No smoking after 8:00 p.m. <i>Log Sheet – Day 7</i>	December 8 <i>Report to Bellomy at 8:30 a.m. with completed log sheet (Test Visit 5)</i> <i>Record # cigarettes smoked</i> <i>Log Sheet – Day 1</i>	December 9 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 2</i>	December 10 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 3</i>

Study Contact Information:

If you have any questions regarding scheduling, study related medical concerns, study instructions, product and/or supplies, please call the 24-hour study # at **336-480-8321**.

December 2011

Thursday Test

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
December 11 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 4</i>	December 12 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 5</i>	December 13 <i>Record # of cigarettes smoked</i> <i>Log Sheet – Day 6</i>	December 14 <i>Record # of cigarettes smoked.</i> No smoking after 8:00 p.m. <i>Log Sheet – Day 7</i>	December 15 <i>Report to Bellomy at 8:30 a.m. with completed log sheet (Make-up Visit)</i> <i>Record # cigarettes smoked</i>	December 16	December 17

Study Contact Information:

If you have any questions regarding scheduling, study related medical concerns, study instructions, product and/or supplies, please call the 24-hour study # at **336-480-8321**.

16.1.4 List and Description of Investigators and Other Important Participants in the Study

Gregory P. Tarleton, PharmD, MD, was the Principal Investigator for this single-center study; his curriculum vitae is provided on the following pages.

A listing of other important participants in the study is provided in the table below.

List of Other Important Participants		
Other Important Participants	Role	Contact Information
Bellomy Research and Clinical Trials of America, Inc.	Study center: Bellomy Research: <ul style="list-style-type: none"> • Subject recruitment • Site reception • Subject payment • Facility management Clinical Trials of America: <ul style="list-style-type: none"> • Screened and enrolled subjects • Conducted study procedures per protocol 	Bellomy Research 4305 Enterprise Drive, Suite E Winston-Salem, NC 27106 Phone: 336-741-6877 Website: www.bellomyresearch.com Clinical Trials of America 215 Executive Park Boulevard Winston-Salem, NC 27103 Phone: 336-768-3456 Website: ctamerica.net
Comprehensive Clinical Development, Inc.	Clinical research organization: <ul style="list-style-type: none"> • Project management • Data management • Statistical analysis • Medical writing 	Corporate Headquarters: 3100 SW 145 th Avenue Miramar, FL 33027 Phone: 954-266-2620 Website: www.comprehensivecd.com
Clinical Ink, Inc.	Electronic source records & Database: <ul style="list-style-type: none"> • Electronic source records design • Data management 	100 North Cherry Street, Suite 520 Winston-Salem, NC 27101 Phone: 336-714-7402 Website: www.clinicalink.com Email: dpierce@clinicalink.com
Phyllis Layfield, BS Trio Clinical Research, LLC	Study monitor: <ul style="list-style-type: none"> • Responsible for all clinical monitoring duties (site initiation visit, interim monitoring visits, and site close-out visit) 	8045 Arc Corporate Drive, Suite 200 Raleigh, NC 27617 Phone: 336-992-6391 Email: playfield@triad.rr.com
Celerion	Bioanalytical laboratory: <ul style="list-style-type: none"> • Assayed serum samples for nicotine and cotinine concentrations 	621 Rose Street Lincoln, NE 68502 Contact: Joan Folbrecht Phone: 402-437-1158 Email: Joan.Folbrecht@celerion.com Website: celerion.com
Solstas Lab Partners	Clinical Safety Laboratory: <ul style="list-style-type: none"> • Analyzed specimens for all clinical laboratory tests 	4380 Federal Drive, Suite 100 Greensboro, NC 27410 Phone: 336-664-6100 Website: www.spectrumlab.org

Curriculum Vitae

Name	Gregory Paul Tarleton, MD	
Address	Business	Clinical Trials of America, Inc. 215 Executive Park Blvd Winston-Salem, NC 27103
Personal Information	Birth Date	(b) (6)
	Birth Place	(b) (6)
	Citizenship	(b) (6)
	Licensure	(b) (6)
Board Certification	2003	American Board of Emergency Medicine
Education	1989 - 1991	University of Georgia Athens, GA BS - Zoology / Pre-pharmacy
	1991 - 1995	Mercer University Southern School of Pharmacy Atlanta, GA Pharm D - Magna Cum Laude
	1995 - 1999	Medical College of Georgia Augusta, GA MD - Summa Cum Laude
Post Doctoral Training	1999 - 2000	Bowman Gray School of Medicine Winston-Salem, North Carolina Internship, Emergency Medicine
	2000 - 2001	Bowman Gray School of Medicine Winston-Salem, North Carolina Residency, Emergency Medicine
	2001 - 2002	Bowman Gray School of Medicine Winston-Salem, North Carolina Chief Resident, Emergency Medicine
Work Experience	2008 - Present	Clinical Trials of America, Inc. 215 Executive Park Blvd Winston-Salem, NC 27103 Clinical Investigator / Medical Director
	2003 - 2008	ALL-TRIALS Clinical Research, LLC Winston-Salem, NC 27103 Clinical Investigator
	2002 - Present	Forsyth Emergency Services, PA Forsyth Medical Center Winston-Salem, NC 27113-5856 Staff Physician
	2001 - 2006	Northern Hospital Of Surry County Mt. Airy, NC Staff Physician
Hospital Affiliation	Forsyth Medical Center	
Research Experience	Community Acquired Pneumonia (Inpatient and Outpatient), Stroke, Stroke Prevention, MI, Atrial Fibrillation, Thromboembolic Disease, Irritable Bowel Syndrome, Ankle Sprain, Asthma/COPD, Insomnia, Osteoarthritis, Sepsis, Skin and Soft Tissue Infection, Diabetes, complicated UTI, Hypertension, Daytime Sleepiness, Restless Leg Syndrome, Obstructive Sleep Apnea, Constipation, Alzheimer's Disease, DVT/VTE, Arthritis, Obesity, Non Restorative Sleep, Multiple Sclerosis, Biomarkers of Effect from Chronic Tobacco Usage, Human Smoking Behavior & Physiological Endpoints when Smoking Three COTAN Prototypes and a Low Tar Control Cigarette, Assessments of Serum Nicotine Exposure from Modern Smoke Free Tobacco Products	

Signature

Date

Gregory P. Tarleton 5-24-10
Gregory P. Tarleton 7/2/11

16.1.5 Signatures

16.1.5.1 Signature of Sponsor's Responsible Medical Officer or Principal or Coordinating Investigator(s)

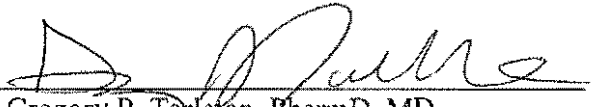
Principal Investigator's Signature

Study Title: Assessment of Smokers' Nicotine Uptake and Urge to Smoke After Use of Smokeless Tobacco Products

Study Number: CSD1101

I have read this report and confirm that to the best of my knowledge it accurately describes the conduct and results of the study.

Signed: _____


Gregory P. Tarleton, PharmD, MD

Date: _____

1/28/2013

16.1.5.2 Signatures of the Clinical Study Report Authors

The signatures of the study report authors and responsible statisticians are provided below.

Study Title: Assessment of Smokers' Nicotine Uptake and Urge to Smoke After Use of
Smokeless Tobacco Products

Study Number: CSD1101

We, the undersigned, confirm that this final clinical study report accurately describes the
experimental methods and results.


Signed: Kelly M. Harger Date: 14 Jan 2013
Kelly M. Harger, BSc
Senior Staff Scientist
Product Integrity, R&D
R.J. Reynolds Tobacco Company

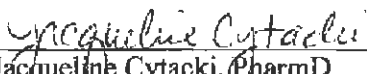
Signed: Mitchell F. Stiles Date: 1/14/2013
Mitchell F. Stiles, MBA
Master Scientist
Product Integrity, R&D
R.J. Reynolds Tobacco Company

Signed: Leanne C. Lee Date: 1/14/2013
Leanne C. Lee, PhD
Senior Scientist, Biostatistician
Product Integrity, R&D
R.J. Reynolds Tobacco Company

Signed: Michael F. Borgerding Date: 14 Jan 2013
Michael F. Borgerding, PhD
Senior Director
Product Integrity, R&D
R.J. Reynolds Tobacco Company

Signed: Eckhardt Schmidt Date: 14 Jan 2013
Eckhardt Schmidt, PhD
Master Scientist, Bioanalysis
Product Integrity, R&D
R.J. Reynolds Tobacco Company

Signed:  Date: 08 Jan 2013
Fei Wang, PhD
Lead Statistician
Comprehensive Clinical Development, Inc.

Signed:  Date: 08 Jan 2013
Jacqueline Cytacki, PharmD
Medical Writer
Comprehensive Clinical Development, Inc.

16.1.6 Listing of Subjects Receiving Study Products from Specific Batches

A listing of subjects receiving study product from specific lots is provided in the table below.

(b) (4)



16.1.7 Randomization Scheme and Codes

The randomization scheme is provided on the following page.

R.J. Reynolds Tobacco Company - CSD1101 ACTUAL RANDOMIZATION SCHEDULE
Assessment of Smokers' Nicotine Uptake and Urge to Smoke After Use of Smokeless Tobacco Products

CONFIDENTIAL

(b) (4)



16.1.8 Audit Certificate(s)

No quality assurance audits were performed during study conduct.

Celerion and Independent IRB, Inc. were audited following completion of study conduct, and this clinical study report was audited. Audit certificates are provided on the following pages.

--CONFIDENTIAL--

R.J. Reynolds Tobacco Company

Audit Certificate

<i>Audit Type:</i> Bioanalytical Services	<i>Protocol Numbers:</i> CSD1007 and CSD1101
<i>Laboratory:</i> Celerion 621 Rose Street Lincoln, NE 68502	
<i>Audit Organization:</i> Quality and Compliance Consulting, Inc. 409 W. Olympic Blvd, Suite 708 Los Angeles, CA 90015	<i>Dates of Audit:</i> 13-15 March 2012

This certificate acknowledges that an audit was conducted at the above laboratory with respect to the protocols indicated.

Auditor: Mark Stiles, Senior Consultant

Audit Certificate Issued By: Jason Bertram, Director of Operations

Signature: 

Date: 11 April 2012

--CONFIDENTIAL--

R.J. Reynolds Tobacco Company

Audit Certificate

Audit Type: Human Research Subject
Protection Board

Protocol Numbers: CSD1008 and CSD1101

IRB:

Independent IRB, Inc.
A Schulman Company
1550 Sawgrass Corporate Parkway, Suite 120
Sunrise, FL 33323

Audit Organization:

Quality and Compliance Consulting, Inc.
409 W. Olympic Blvd, Suite 708
Los Angeles, CA 90015

Dates of Audit:

15-16 August 2012

This certificate acknowledges that an audit was conducted at the above IRB with respect to the protocols indicated.

Auditor: Richard Todd, Senior Consultant

Audit Certificate Issued By: Jason Bertram, Director of Operations

Signature:

Date:

19 Sep 2012

--CONFIDENTIAL--

R.J. Reynolds Tobacco Company

Audit Certificate

Audit Type: GCP Audit of Clinical Study Report	Protocol Number: CSD1101
Clinical Study Report Version Audited: Draft Version 4.0, 07 December 2012	
Audit Organization: Quality and Compliance Consulting, Inc. 409 W. Olympic Blvd, Suite 708 Los Angeles, CA 90015	Dates of Audit: 11-14 December 2012

This certificate acknowledges that an audit was conducted of the Clinical Study Report for the protocol indicated.

Auditors: Jason Bertram, Director of Operations
Sirinda Sincharoen, Ph.D., Operations Manager

Audit Certificate Issued By: Jason Bertram, Director of Operations

Signature: 

Date: 19 Dec 2012

16.1.9 Documentation of Statistical Methods

The [Statistical Analysis Plan](#) is provided on the following pages.

R.J. Reynolds Tobacco Company
Research and Development
Clinical Studies Division
P.O. Box 1487
Winston-Salem, North Carolina 27102

Protocol CSD1101

Assessment of Smokers' Nicotine Uptake and Urge to Smoke After Use of Smokeless
Tobacco Products

February 17, 2012

Statistical Analysis Plan Version Final V1
Protocol version: 1.0, 22 July 2011

Prepared by:
Comprehensive Clinical Development
One Copley Parkway, Suite 534
Morrisville, NC 27560

Issued by:

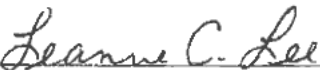


Fei Wang, PhD
Lead Statistician
Comprehensive Clinical Development

Date: 02/22/2012

Upon review of this document, including table, listing, and figure shells, the undersigned approves the statistical analysis plan. The analysis methods and data presentation are acceptable, and the table, listing, and figure production can begin.


Approved by:



Leanne C. Lee, PhD
Senior Scientist, Biostatistics
Product Integrity, R&D

Date: 02/21/2012

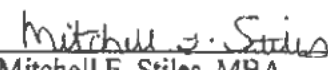
Approved by:



Kelly M. Harger
Senior Scientist
Product Integrity, R&D

Date: 02/21/2012

Approved by:



Mitchell F. Stiles, MBA
Senior Manager
Product Integrity, R&D

Date: 02/21/2012

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List of Abbreviations

AE	adverse event
ANOVA	analysis of variance
AUC _{0-∞}	Area under the plasma concentration time curve from time zero to infinity
AUC ₀₋₁₈₀	area under the observable concentration-versus-time curve
AUC _{adj}	baseline-adjusted area under the concentration-versus-time curve
AUC _{ratio}	Ratio of AUC _{adj} for smokeless products and AUC _{adj} for cigarette
AUC _{STP}	Baseline-adjusted AUC for smokeless tobacco product
AUC _{UB}	Baseline-adjusted cigarette AUC
BLQ	Below limit of quantification
C _{last}	Last observable concentration
C _{max}	maximum concentration
C _{max(adj)}	baseline-adjusted maximum concentration
C _t	observed concentration at time <i>t</i>
CCD	Comprehensive Clinical Development
CPD	cigarettes per day
ECO	expired carbon monoxide
FTND	Fagerström Test for Nicotine Dependence
IQR	interquartile range
IV	Intravenous
λ _{el}	Terminal elimination rate
LS	least squares
MPSS	Mood and Physical Symptoms Scale
RJRT	R.J. Reynolds Tobacco Company
RTF	rich text format
SAP	Statistical Analysis Plan
SQRT	square root
STM	simplified tobacco material
STP	smokeless tobacco product
T _{last}	Time of last observable concentration
T _{max}	time to maximum concentration
UB	usual brand

Text Revisions

Date/Version	Section(s)	Change

1 Administrative Structure

This study will be conducted under the sponsorship of R.J. Reynolds Tobacco Company (RJRT). Clinical conduct will be overseen by RJRT and statistical analysis will be performed by Comprehensive Clinical Development (CCD). Data management will be performed under contract with CCD.

2 Introduction

This study of smokeless tobacco products (STPs) will evaluate, in five separate test visits, the serum nicotine uptake and tobacco abstinence symptoms for subjects after a 12-hour tobacco and nicotine abstinence period. Measures will be obtained prior to and following in-clinic use of a single unit of usual brand (UB) cigarette and each of four STPs: Camel SNUS and (b) (4)

3 Objectives

The objectives of this study are to assess the following after a 12-hour tobacco and nicotine abstinence period:

- Nicotine uptake in blood over a three-hour period with respect to in-clinic study product administration.
- Tobacco abstinence symptoms over a three-hour period with respect to in-clinic study product administration.

4 Investigational Plan

4.1 Overall Study Design and Plan

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(b) (4)

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Note: Subjects will consume a single unit of each study product: usual brand cigarette, (b) (4)
(b) (4), and Camel SNUS.

Figure 1: Overall Study Design

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4.2 Study Endpoints

4.2.1 Biomarker Assessments

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4.2.2 Questionnaires

The Fagerström Test for Nicotine Dependence (FTND) will be collected only at screening.

The Mood and Physical Symptoms Scale (MPSS) will be completed at screening and then 10 times at each test visit. The first MPSS questionnaire administered to a subject at each test visit will be completed prior to attempting IV catheter insertion. All other MPSS questionnaire administrations will occur with respect to the start time of in-clinic product administration, including 5, 15, 30, 45, 60, 90, 120, 150, and 180 minutes afterwards.

4.2.3 Expired Carbon Monoxide (ECO)

ECO will be measured at screening to confirm that subjects inhale cigarette smoke. In addition, ECO will be measured at the start of each test visit to verify smoking abstinence.

4.2.4 Safety Assessments

Safety will be assessed by monitoring AEs, physical examinations (including an oral exam), clinical laboratory tests, and vital sign measurements.

5 General Statistical Considerations

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5.1 Sample Size

The sample size planned for the study is based on existing knowledge and research experience. Based on the requirements of the randomization method (i.e., Williams Design), the target number for completion of this study is a minimum of 16 subjects.

5.2 Subject Samples

(b) (4)



5.3 Changes in the Protocol Planned Analysis

None.

6 Statistical Analysis Methods

6.1 Serum Nicotine

(b) (4)



6.1.1 Baseline Adjustment

(b) (4)



6.1.2 Comparison of AUC_{0-180} to $AUC_{0-\infty}$ and λ_{el}

(b) (4)



6.2 Mood and Physical Symptoms Scale (MPSS)

For the secondary objective of evaluating abstinence symptoms, paired t-tests will be used to assess changes in tobacco abstinence symptom responses (MPSS items) before vs. after product use for each of the products. P-values and mean differences from pre-product use will be presented in the tables.

Descriptive statistics will be provided for each MPSS item.

Plots of mean scores over time will also be presented by product.

² Concentrations at the following time points will be adjusted: 3, 5, 7.5, 10, 15, 20, 30, 45, 60, 75, 90, 120, 150, and 180 minutes.

³ In the event that the value at time 0 is missing or unavailable, the pre-0 value will be substituted.

Raw MPSS data will also be presented in listing format.

6.3 Serum Cotinine

A mixed model ANOVA will be used to evaluate starting cotinine levels (time 0⁴ only) between products. Product will be the fixed effect and subject will be the random effect. For all pairwise product comparisons, p-values will be provided. The Gaussian assumption will be verified by visually inspecting the quantile-quantile plot of residuals from the model. If necessary, a natural log transformation will be performed to achieve normally-distributed residuals.

Descriptive statistics will be provided for cotinine at time 0 and will include Q₁, Q₃, and either LS means or geometric LS means, depending on how cotinine is analyzed (i.e., on the original or log scale).

A notched boxplot (see [section 9.1](#) for description) will be produced to descriptively compare cotinine at time 0 for each product.

Cotinine concentrations for all time points will also be presented in listing format.

6.4 Camel SNUS and STMs AUC as a Percentage of UB AUC (AUC_{ratio})

(b) (4)



⁴ Pre-0 value will be substituted if the value at time 0 is missing.

6.5 Product Usage Time

A notched boxplot will be produced for Product Usage Time. Descriptive statistics will be provided for usage time for each product, and product usage time will be presented in listing format.

6.6 Expired Carbon Monoxide

ECO will be presented in listing format.

7 Subject Disposition

Enrolled subjects, completed subjects, and reasons for discontinuation will be listed.

8 Demographics and Background Characteristics

8.1 Demographics

Descriptive statistics will be calculated for continuous demographics (age, height, and weight). Frequency count and percentage will be tabulated for sex, ethnicity, and race. Number of years smoked, cigarettes per day (CPD, self-reported at screening), scores for the Fagerström Test for Nicotine Dependence (FTND), and Mood and Physical Symptom Scale (MPSS) ratings reported at screening will also be summarized using descriptive statistics.

Demographics, years smoked, self-reported CPD, FTND scores, and MPSS responses reported at screening will also be presented in listing format.

8.2 Usual Brand Descriptor Information

Frequency counts and percentages will be reported for Usual Brand Descriptor Information.

Usual Brand Descriptor Information will also be presented in listing format.

8.3 Medical History

Subject reported medical history information will be presented in listing format.

9 Cigarette Usage and Concomitant Medications

Usual Brand usage data (collected during the study) and concomitant medication usage will each be presented in listing format.

10 Safety Analysis

10.1 Adverse Events

Any untoward medical occurrence experienced by an enrolled subject, whether or not considered tobacco product-related by the investigator, will be recorded on an electronic Adverse Event form. Adverse events will be coded using MedDRA Version 14.1. Adverse events will be temporally attributed to the last product received prior to adverse event occurrence. Adverse events occurring more than 7 days after the final product administration will not be included in the summary of adverse events.

A table summarizing the incidence of adverse events (as defined above) by product group will count a given coded event (preferred term) once per subject - similarly for system organ classifications. Percentages will be based on the number of subjects receiving each product.

All events captured in the database will be listed in by-subject listings. This listing will include verbatim term, preferred term, type, frequency, severity, relationship to study product, action taken, treatment, onset date and time, and end date and time.

Adverse events leading to study termination will also be listed by subject.

10.2 Clinical Laboratory Evaluations

Clinical laboratory tests will be performed at the Screening Visit and at Test Visit 5 (or early termination). The PI will notify the Sponsor if repeat laboratory testing is needed. Clinical laboratory tests will include the following:

- **Complete blood count (CBC):** hematocrit, hemoglobin, mean corpuscular hemoglobin, mean corpuscular hemoglobin concentration, mean corpuscular volume, platelet count, red blood cell distribution width, red blood cell count, and white blood cell count
- **Comprehensive metabolic profile (CMP):** albumin, alkaline phosphatase, alanine aminotransferase, aspartate aminotransferase, blood urea nitrogen, calcium, chloride, carbon dioxide, creatinine, glucose, potassium, sodium, total bilirubin, and total protein
- **Urinalysis (macroscopic):** urine color and appearance, urine pH, urine specific gravity, urine bilirubin, urine glucose, urine ketones, urine leukocytes, urine nitrite, urine protein, occult blood, and urobilinogen
- **Triglycerides**
- **Total Cholesterol**

These results will be listed but not summarized in tables.

10.3 Vital Signs

Blood pressure will be collected at each visit and will be presented in listing format.

10.4 Oral Health and Physical Exam

An oral health examination and a physical examination will be performed at Screening and Test Visit 5 or early termination.

Results from these examinations will be presented in listing format only.

11 Interim Analysis

None planned.

12 References

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Listing 16.2.6.5	Fagerström Test
Listing 16.2.7.1	Adverse Events
Listing 16.2.7.2	Serious Adverse Events
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Figure 14.3.1	Individual Mood and Physical Symptoms Scale Items vs Time, All Randomized Subjects

Table

Change

Confidential
Table 14.1.1
Subject Disposition

	All Randomized Subjects (N = xx)
Completed the Study	nn (nn.n%)
Discontinued from the Study	nn (nn.n%)
Reason for Discontinuation	
Adverse Event, specify	nn (nn.n%)
Protocol Noncompliance, specify	nn (nn.n%)
Consent Withdrawn	nn (nn.n%)
Lost to follow-up	nn (nn.n%)
Pregnancy	nn (nn.n%)
Inability to communicate and/or unwillingness to cooperate with the investigator, specify	nn (nn.n%)
Change in status with respect to an I/E criterion that is clinically relevant and/or could affect subject safety, specify	nn (nn.n%)
Other, specify	nn (nn.n%)

Data Source: [Listing 16.2.1](#)

Program: N:/CDD/CLIENT/STUDY/STAT/PROGRAM/TXXX.SAS Executed: DDMMYYYY HH:MM

Confidential
Table 14.1.2
Demographics and Characteristics at Screening

	All Randomized Subjects (N = xx)
Sex	
Female	nn (nn.n%)
Male	nn (nn.n%)
Age (years)	
n	xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
Min, Max	xx, xx
Race	
African American	nn (nn.n%)
American Indian	nn (nn.n%)
Asian	nn (nn.n%)
Caucasian	nn (nn.n%)
Hispanic/Latino	nn (nn.n%)
Native Hawaiian	nn (nn.n%)

Data Source: [Listing 16.2.3.1](#), [16.2.6.1](#), and [16.2.6.5](#)

Program: N:/CDD/CLIENT/STUDY/STAT/PROGRAM/TABLE/TXXX.SAS Executed: DDMMYYYY HH:MM

Confidential
Table 14.1.2
Demographics and Characteristics at Screening

	All Randomized Subjects (N = xx)
Height (in)	
n	xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
Min, Max	xx, xx
Weight (lb)	
n	xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
Min, Max	xx, xx
Mood and Physical Symptoms Scale Item 1: Depressed	
n	xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
Min, Max	xx, xx
Mood and Physical Symptoms Scale Item 2: Anxious	
n	xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
Min, Max	xx, xx
Mood and Physical Symptoms Scale Item 3: Irritable	
n	xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
Min, Max	xx, xx

Data Source: [Listing 16.2.3.1](#), [16.2.6.1](#), and [16.2.6.5](#)

Program: N:/CDD/CLIENT/STUDY/STAT/PROGRAM/TABLE/TXXX.SAS Executed: DDMMYYYY HH:MM

Confidential
Table 14.1.2
Demographics and Characteristics at Screening

	All Randomized Subjects (N = xx)
Mood and Physical Symptoms Scale Item 4: Restless	
n	xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
Min, Max	xx, xx
Mood and Physical Symptoms Scale Item 5: Hungry	
n	xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
Min, Max	xx, xx
Mood and Physical Symptoms Scale Item 6: Poor Concentration	
n	xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
Min, Max	xx, xx
Mood and Physical Symptoms Scale Item 7: How strong is your current urge to smoke?	
n	xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
Min, Max	xx, xx

Data Source: [Listing 16.2.3.1](#), [16.2.6.1](#), and [16.2.6.5](#)

Program: N:/CDD/CLIENT/STUDY/STAT/PROGRAM/TABLE/TXXX.SAS Executed: DDMMYYYY HH:MM

Confidential
Table 14.1.2
Demographics and Characteristics at Screening

	All Randomized Subjects (N = xx)
Fagerstrom Q1: How soon after you wake up do you smoke your first cigarette?	
Within 5 Minutes	nn (nn.n%)
6-30 Minutes	nn (nn.n%)
31-60 Minutes	nn (nn.n%)
After 60 Minutes	nn (nn.n%)
Fagerstrom Q2: Do you find it difficult to refrain from smoking in places where it is forbidden, eg in church, at the library, in cinema, etc?	
Yes	nn (nn.n%)
No	nn (nn.n%)
Fagerstrom Q3: Which cigarette would you hate most to give up?	
The First One in the Morning	nn (nn.n%)
Any Other	nn (nn.n%)
Fagerstrom Q4: How many cigarettes per day do you smoke?	
<=10	nn (nn.n%)
11-20	nn (nn.n%)
21-30	nn (nn.n%)
>=31	nn (nn.n%)

Data Source: [Listing 16.2.3.1](#), [16.2.6.1](#), and [16.2.6.5](#)

Program: N:/CDD/CLIENT/STUDY/STAT/PROGRAM/TABLE/TXXX.SAS Executed: DDMMYYYY HH:MM

Confidential
Table 14.1.2
Demographics and Characteristics at Screening

	All Randomized Subjects (N = xx)
Fagerstrom Q5: Do you smoke more frequently during the first hours after waking than during the rest of the day?	
Yes	nn (nn.n%)
No	nn (nn.n%)
Fagerstrom Q6: Do you smoke if you are so ill that you are in bed most of the day?	
Yes	nn (nn.n%)
No	nn (nn.n%)
Fagerstrom Total Score	
n	xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
Min, Max	xx, xx

Data Source: [Listing 16.2.3.1](#), [16.2.6.1](#), and [16.2.6.5](#)

Program: N:/CDD/CLIENT/STUDY/STAT/PROGRAM/TABLE/TXXX.SAS Executed: DDMMYYYY HH:MM

Confidential
Table 14.1.3
Usual Brand Summary

	All Randomized Subjects (N = xx)
Usual Brand Name	
XXXXXXXXXXXXXXXX	nn (nn.n%)
XXXXXXXXXXXXXXXX	nn (nn.n%)
XXXXXXXXXXXXXXXX	nn (nn.n%)
XXXXXXXXXXXXXXXX	nn (nn.n%)
Length	
85 mm (King-size)	nn (nn.n%)
83 mm (King-size)	nn (nn.n%)
99 mm	nn (nn.n%)
100 mm	nn (nn.n%)
72 mm (excludes)	nn (nn.n%)
120 mm (excludes)	nn (nn.n%)
Packaging	
Soft-pack	nn (nn.n%)
Hard-pack (box)	nn (nn.n%)
Type	
Menthol	nn (nn.n%)
Non-menthol	nn (nn.n%)
Filter Type	
Standard	nn (nn.n%)
Non-filtered (excludes)	nn (nn.n%)
Number of cigarettes the subject typically smokes per day	
n	xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
Min, Max	xx, xx
Length of time subject has smoked (years)	
n	xx
Mean (SD)	xx.x (xx.xx)
Median	xx.x
Min, Max	xx, xx

Data Source: [Listing 16.2.3.2](#)

Confidential

Table 14.1.4

In-clinic Product Use Duration (minutes) - Summary by Product Group

(b) (4)



Confidential

Table 14.2.1.1

Serum Concentrations - Summary by Product and Time Point for Cotinine (pre-product only) and Nicotine

(b) (4)



Confidential
Table 14.2.1.2

Summary of Derived Nicotine Uptake Parameters and Cotinine at Time 0 by Product Group

(b) (4)



Confidential
Table 14.2.1.3

Summary of Pairwise Comparisons for Derived Nicotine Uptake Parameters and Cotinine at Time 0

(b) (4)



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Table 14.2.2.1

Mood and Physical Symptoms Scale - Summary by Product Group Over Time

(b) (4)



Confidential

Table 14.2.2.2

Mood and Physical Symptoms Scale - Summary of Paired t-tests

(b) (4)



Confidential
Table 14.3.1

Adverse Events - Number and Percentage of Subjects
by System Organ Class, Preferred Term, and Product Group

(b) (4)



Listing

Change

Confidential
Listing 16.2.1
Subject Disposition

(b) (4)



Confidential
Listing 16.2.2
Exclusion Tests - Drug Screen and Pregnancy

(b) (4)



Confidential
Listing 16.2.3.1
Demographics and Screening Characteristics

(b) (4)



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Listing 16.2.3.2
Usual Brand

(b) (4)



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Listing 16.2.3.3
Medical History

(b) (4)



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Listing 16.2.3.4
Concomitant Medications

(b) (4)



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Listing 16.2.3.5
Cigarette Usage

(b) (4)



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Listing 16.2.5.1
Serum Concentrations

Subject	Product	Age/Sex/Race	Analyte	Collection Date/ Time	Scheduled Time Point	Concentration	Units
				DDMMYYYY/ HH:MM:SS			

Program: N:/CDD/CLIENT/STUDY/STAT/PROGRAM/LISTING/LXXX.SAS Executed: DDMMYYYY HH:MM

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Listing 16.2.5.2
Derived Nicotine Uptake Parameter Estimates

Subject	Product	Age/Sex/Race	AUC ₀₋₁₈₀	AUC _{adj}	C _{max}	C _{max (adj)}	T _{max}	AUC _{ratio}	λ _{el}
---------	---------	--------------	----------------------	--------------------	------------------	------------------------	------------------	----------------------	-----------------

Program: N:/CDD/CLIENT/STUDY/STAT/PROGRAM/LISTING/LXXX.SAS Executed: DDMMYYYY HH:MM

Confidential
Listing 16.2.5.3
Product Administration

Subject	Age/Sex/Race	Visit	Product	Start timed use	Stop timed use	Usage Time (min)
				HH:MM:SS	HH:MM:SS	xxx.x

Subject	Product	Age/Sex/Race	Date/Time	Visit/						Poor	Current Urge
			Obtained	Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Concentration {1}	to Smoke {2}
XXX	XXX	XX/X/XX	DDMMYYYY	Screening	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XX/X/XX	DDMMYYYY/HH:MM:SS	X/XX	XXX	XXX	XXX	XXX	XXX	XXX	XXX

{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely
{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

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Listing 16.2.6.2
Expired Carbon Monoxide Results

(b) (4)



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Listing 16.2.6.4
Oral Health and Physical Examination

Subject	Age/Sex/Race	Visit	Date	Exam	Result
			Obtained	Item	

XXX	XX/X/XX		DDMMYYYY	XXX	
-----	---------	--	----------	-----	--

Confidential
Listing 16.2.6.5
Fagerström Test

-
-
- (1) How Soon after you wake up do you smoke your first cigarette? (0) after 60 minutes (1) 31 - 60 minutes (2) 6-30 minutes
(3) within 5 minutes
- (2) Do you find it difficult to refrain from smoking in places where it is forbidden, e.g., in church, at the library,
in cinema, etc.? (0) No (1) Yes
- (3) Which cigarette would you hate most to give up? (1) The first one in the morning (0) Any other.
- (4) How many cigarettes per day do you smoke? (0) <=10 (1) 11-20 (2) 21-30 (3) >=31
- (5) Do you smoke more frequently during the first hours after waking than during the rest of the day? (0) No (1) Yes
- (6) Do you smoke if you are so ill that you are in bed most of the day? (0) No (1) Yes
-

Confidential
Listing 16.2.6.5
Fagerström Test

(b) (4)



Confidential
Listing 16.2.7.1
Adverse Events

-
-
- (1) From the MedDRA dictionary, Version 14.1
- (2) Relative Start/Stop Day is calculated relative to the day of enrollment, where Relative Start/Stop Day 1 refers to day of the enrollment and Relative Start/Stop Day -1 refers to the day prior to the day of enrollment.
If start/stop date is on or after the date of enrollment then Relative Start/Stop Day = start/stop date - enrollment date + 1. If the start/stop date is before the date of enrollment, then Relative Start/Stop Day = start/stop date - enrollment date.
- (3) Type: ECG; Lab; Other
- (4) Frequency: 1 = Continuous; 2 = Intermittent; 3 = Single-Episode
- (5) Severity: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening; 5=Death
- (6) Treatment Required? 0=None; 1=Concomitant Meds; 3=Non-Drug Therapies and Concomitant Meds; 4=Hospitalization
- (7) Action Taken Select with Study Product and/or Subject: 1 = None; 2 = Interrupted; 3 = Discontinued
- (8) Relationship to Study Product: 1 = Definite; 2 = Probable; 3 = Possible; 4 = Unlikely; 5 = Unrelated
- (9) Serious adverse event: Y= Yes; N= No?
- (10) Ongoing (at the end of the study): Y = Yes; N = No
- (11) Outcome: 1 = Resolved; 2 = Resolved w/Sequelae; 3 = Continuing; 4 = Fatal
-
-

Confidential
Listing 16.2.7.1
Adverse Events

Subject	Product	Age/Sex/Race	System Organ Class (1)/	Onset	Resolved	Relative		Frequency	Severity	Treatment	Action		Relationship	Serious	Ongoing	Outcome
			Preferred Term (1)/	Date/	Date/	Start, Stop	Type				Required?	(6) (7)				
			Verbatim Term/	Time	Time	Day (2)	(3)	(4)	(5)				(8)	(9)	(10)	(11)
XXX	XXX	XX/X/XX	XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXX	DDMMYYYY/ HH:MM	DDMMYYYY/ HH:MM	XX, XX		X	X			X	X	X	X	X

Note: Refer to page 1 of Listing 16.2.7.1 for footnotes.

Confidential
Listing 16.2.7.2
Serious Adverse Events

-
-
- (1) From the MedDRA dictionary, Version 14.1
 - (2) Relative Start/Stop Day is calculated relative to the day of enrollment, where Relative Start/Stop Day 1 refers to day of the enrollment and Relative Start/Stop Day -1 refers to the day prior to the day of enrollment.
If start/stop date is on or after the date of enrollment then Relative Start/Stop Day = start/stop date - enrollment date + 1. If the start/stop date is before the date of enrollment, then Relative Start/Stop Day = start/stop date - enrollment date.
 - (3) Type: ECG; Lab; Other
 - (4) Frequency: 1 = Continuous; 2 = Intermittent; 3 = Single-Episode
 - (5) Severity: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening; 5=Death
 - (6) Treatment Required? 0=None; 1=Concomitant Meds; 3=Non-Drug Therapies and Concomitant Meds; 4=Hospitalization
 - (7) Action Taken Select with Study Product and/or Subject: 1 = None; 2 = Interrupted; 3 = Discontinued
 - (8) Relationship to Study Product: 1 = Definite; 2 = Probable; 3 = Possible; 4 = Unlikely; 5 = Unrelated
 - (9) Serious adverse event: Y= Yes; N= No?
 - (10) Ongoing (at the end of the study): Y = Yes; N = No
 - (11) Outcome: 1 = Resolved; 2 = Resolved w/Sequelae; 3 = Continuing; 4 = Fatal
-
-

Confidential
Listing 16.2.7.2
Serious Adverse Events

Subject	Product	Age/Sex/Race	System Organ Class (1)/	Onset	Resolved	Relative		Frequency	Severity	Treatment	Action		Relationship	Serious	Ongoing	Outcome
			Preferred Term (1)/ Verbatim Term/	Date/ Time	Date/ Time	Start, Stop Day (2)	Type (3)				Required? (6)	(7)				
XXX	XXX	XX/X/XX	XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXX	DDMMYYYY/ HH:MM	DDMMYYYY/ HH:MM	XX, XX		X	X			X	X	X	X	X

Note: Refer to page 1 of Listing 16.2.7.2 for footnotes.

Confidential
Listing 16.2.7.3
Adverse Events Leading to Cessation or Interruption of Usage

-
-
- (1) From the MedDRA dictionary, Version 14.1
- (2) Relative Start/Stop Day is calculated relative to the day of enrollment, where Relative Start/Stop Day 1 refers to day of the enrollment and Relative Start/Stop Day -1 refers to the day prior to the day of enrollment.
If start/stop date is on or after the date of enrollment then Relative Start/Stop Day = start/stop date - enrollment date + 1. If the start/stop date is before the date of enrollment, then Relative Start/Stop Day = start/stop date - enrollment date.
- (3) Type: ECG; Lab; Other
- (4) Frequency: 1 = Continuous; 2 = Intermittent; 3 = Single-Episode
- (5) Severity: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening; 5=Death
- (6) Treatment Required? 0=None; 1=Concomitant Meds; 3=Non-Drug Therapies and Concomitant Meds; 4=Hospitalization
- (7) Action Taken Select with Study Product and/or Subject: 1 = None; 2 = Interrupted; 3 = Discontinued
- (8) Relationship to Study Product: 1 = Definite; 2 = Probable; 3 = Possible; 4 = Unlikely; 5 = Unrelated
- (9) Serious adverse event: Y= Yes; N= No?
- (10) Ongoing (at the end of the study): Y = Yes; N = No
- (11) Outcome: 1 = Resolved; 2 = Resolved w/Sequelae; 3 = Continuing; 4 = Fatal
-
-

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Listing 16.2.7.3
Adverse Events Leading to Cessation or Interruption of Usage

Subject	Product	Age/Sex/Race	System Organ Class (1)/	Onset	Resolved	Relative		Frequency	Severity	Treatment	Action		Relationship	Serious	Ongoing	Outcome
			Preferred Term (1)/	Date/	Date/	Start, Stop	Type				Required?	(6) (7)				
			Verbatim Term/	Time	Time	Day (2)	(3)	(4)	(5)				(8)	(9)	(10)	(11)
XXX	XXX	XX/X/XX	XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXX	DDMMYYYY/ HH:MM	DDMMYYYY/ HH:MM	XX, XX		X	X			X	X	X	X	X

Note: Refer to page 1 of Listing 16.2.7.3 for footnotes.

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Listing 16.2.8.1
Complete Blood Count

(b) (4)



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Listing 16.2.8.2

Comprehensive Metabolic Profile, Triglycerides, and Total Cholesterol

(b) (4)



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Listing 16.2.8.3
Urinalysis

(b) (4)



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Listing 16.2.9
Vital Signs

(b) (4)



Figure

Change

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Figure 14.2.1

Boxplot Summary of Serum Nicotine Uptake Parameters

All Randomized Subjects

(b) (4)



R.J Reynolds Tobacco Company

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Figure 14.2.2

Boxplot Summary of Serum Cotinine at Time 0

All Randomized Subjects

(b) (4)



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Figure 14.2.3

Mean Serum Nicotine Concentration vs Time

All Randomized Subjects

(b) (4)



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Figure 14.2.4
Individual Serum Nicotine Concentration vs Time
All Randomized Subjects

Subject: 01

(b) (4)



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Figure 14.3.1

Individual Mood and Physical Symptoms Scale Items vs Time
All Randomized Subjects

(b) (4)



16.1.10 Documentation of Inter-Laboratory Standardization Methods and Quality Assurance Procedure

All safety laboratory analyses were performed by Solstas Lab Partners, 4380 Federal Drive, Suite 100, Greensboro, NC, 27410. Reference ranges are provided on the following pages.

Copies of the CAP and CLIA certificates are provided on the following pages.

**Reference Ranges for Carilion-Spectrum @ Federal Drive
As of 12/31/10**

CHEMISTRY		
Test Name	Adult Reference Range	Units of Measure
Albumin	3.5 – 5.2	g/dL
Alkaline Phosphatase	39 – 117	U/L
ALT / SGPT	Males: 0-53 Females: 0-35	U/L
Amylase	0-105	U/L
AST / SGOT	0-37	U/L
Bilirubin, Direct	0.0-0.3	mg/dL
Bilirubin, Indirect	0.0-0.9	mg/dL
Bilirubin, Total	0.3-1.2	mg/dL
BUN	6-23	mg/dL
Calcium	8.4-10.5	mg/dL
Chloride	96-112	mEq/L
Cholesterol	0-200	mg/dL
CK	Males: 7-232 Females: 7-177	U/L
CKMB	0.3-4.0	ng/mL
CKMB Relative Index	0.0-2.5	
CO2	19-32	mEq/L
Creatinine	Males: 0.40-1.50 Females: 0.40-1.20	mg/dL
Ferritin	Males: 22-322 Females: 10-291	ng/mL
Folate, Serum	0.4-3.3 Deficient 3.4-5.4 Indeterminate >5.4 Normal	ng/mL
Fructosamine	< 285	umol/L
Gamma GT	7-51	U/L
Glucose	70-99	mg/dL
HDL	>39	mg/dL
Hemoglobin A1c	4.6-6.1	%
Homocysteine	4.0-15.4	umol/L
Parathyroid Hormone, Intact	14.0-72.0	pg/mL
Iron / IBC	Males: 42-165 Females: 42-145	ug/dL
LDH	94-250	U/L
Lipase	0-75	U/L
Magnesium	1.5-2.5	mg/dL
Myoglobin	< 111	ng/mL
Phosphorus	2.3-4.6	mg/dL
Potassium	3.5-5.3	mEq/L
Sodium	135-145	mEq/L
Total Protein	6.0-8.3	g/dL
Triglyceride	< 150	mg/dL
Troponin I	< 0.06	ng/mL

Jamie J. Hesler MD PhD
12/30/10

CHEMISTRY con't		
Test Name	Adult Reference Range	Units of Measure
Uric Acid	Males: 4.0-7.8 Females: 2.4-7.0	mg/dL
Vitamin B12	211-911	pg/mL

THERAPEUTIC DRUGS		
Test Name	Adult Reference Range	Units of Measure
Dilantin	10.0-20.0	ug/mL
Phenobarbital	15.0-40.0	ug/mL
Theophylline	10.0-20.0	ug/mL
Vancomycin, Trough	10.0-20.0	ug/mL

IMMUNOSUPPRESSIVE DRUGS		
Test Name	Adult Reference Range	Units of Measure
Cyclosporine	140-330	ng/mL
Tacrolimus	5.0-20.0	ng/mL

HORMONES		
Test Name	Adult Reference Range	Units of Measure
Estradiol	Male: 0 - 52 Female: Menstruating Females (by day in cycle relative to LH peak) Follicular phase (-12) 11-69 (- 4) 63-165 Midcycle (- 1) 146-526 Luteal Phase (+ 2) 33-150 (+6) 68-196 (+12) 36-133 Postmenopausal Females 0-37 (untreated)	pg/mL
FSH	Males: 1.4-18.1 Females: Follicular Phase 2.5-10.2 Midcycle Peak 3.4-33.4 Luteal Phase 1.5-9.1 Post Menopausal 23.0-116.3 Pregnant < 0.3	mIU/mL

HORMONES con't		
Test Name	Adult Reference Range	Units of Measure
HCG Quantitative	Males and Non-Pregnant Females: < 5 During Pregnancy: Gestation Age Concentration ≤ 1 Week 5 – 50 2 Weeks 50 – 500 3 Weeks 100 – 10,000 4 Weeks 1,000 – 30,000 5 Weeks 3,500 – 115,000 6–8 Weeks 12,000 – 270,000 12 Weeks 15,000 – 220,000	mIU/mL
LH	Male: ▪ 20–70 years 1.5–9.3 ▪ > 70 years 3.1–34.6 Female: • Follicular phase 1.9–12.5 • Midcycle 8.7–76.3 • Luteal phase 0.5–16.9 • Post menopausal 15.9–54.0 • Pregnant <1.5 • Contraceptives 0.7–5.6 Children: < 6.0	mIU/mL
Progesterone	Adult Male: 0.3–1.2 Adult Female: • Follicular: 0.2–1.4 • Luteal: 3.3–25.6 • Mid Luteal: 4.4–28.0 • Post Menopausal: 0.0- 0.7	ng/mL
Prolactin	Male: 2.1–17.1 Female: • Pregnant: 9.7–208.5 • Non Pregnant: 2.8–29.2 • Post Menopausal: 1.8–20.3	ng/mL
T3	80.0-204.0	ng/dL
T3, Free	2.3-4.2	pg/mL
T3Uptake	22.5-37.0	%
T4	5.0-12.5	ug/dL
T4, Free	0.80-1.80	ng/dL
TSH	0.350-4.500	uIU/mL

TUMOR MARKERS		
Test Name	Adult Reference Range	Units of Measure
AFP	0.0-8.0	ng/mL
CA 125	0.0-30.2	U/mL
CEA	0.0-5.0	ng/mL
PSA, Total	0.10-4.00	ng/mL
PSA, Free	> 25	%

URINES		
Test Name	Adult Reference Range	Units of Measure
Urinalysis	Color	yellow
	Appearance	clear
	Specific Gravity	1.005-1.030
	pH	5.0-8.0
	Glucose	negative
	Bilirubin	negative
	Ketone	negative
	Blood	negative
	Protein	negative
	Urobilinogen	0.0-1.0
	Nitrite	negative
	Leukocytes	negative
	Bacteria	rare / hpf
24hr Urine Protein	50-100	mg/day
24hr Urine Creatinine	Males: 800-2000 Females: 700-1800	mg/day
Protein / Creatinine Ratio	< 0.15	

IMMUNOLOGY		
Test Name	Adult Reference Range	Units of Measure
ASO	0-116	IU/mL
CEA	0.0-5.0	ng/mL
CRP, C-Reactive Protein	< 0.6	mg/dL
CRP, hs High Sensitivity	< 1.0 Low risk 1.0-3.0 Average risk > 3.0 High risk	mg/L
IgA	68-378	mg/dL
IgG	694-1618	mg/dL
IgM	60-263	mg/dL
Rheumatoid Factor	0-20	IU/mL
Rubella	< 5.0 Not Immune 5.0-9.9 Equivocal ≥ 10.0 Immune	IU/mL
Transferrin	212-360	mg/dL

COAGULATION		
Test Name	Adult Reference Range	Units of Measure
PT	11.6-15.2	Seconds
INR	< 1.50	
PTT	24-37	Seconds
ATIII	76-126	%
D Dimer	0.00-0.48	ug/mL-FEU
Factor II	74-131	%
Factor IX	75-134	%
Factor VIII	73-140	%
Factor X	72-134	%
Fibrinogen	204-475	mg/dL
Protein C Functional	75-133	%
Protein S Functional	69-129	%

HEMATOLOGY		
Test Name	Adult Reference Range	Units of Measure
WBC	4.0-10.5	K/uL
RBC	Males: 4.22-5.81 Females: 3.87-5.11	MIL/uL
HGB	Males: 13.0-17.0 Females: 12.0-15.0	g/dL
HCT	Males: 39.0-52.0 Females: 36.0-46.0	%
MCV	78.0-100.0	fL
MCHC	30.0-36.0	g/dL
RDW	11.5-15.5	%
PLT	150-400	K/uL
%Monocytes	3-12	%
Absolute Monocytes	0.1-1.0	K/uL
% Lymphocytes	12-46	%
Absolute Lymphocytes	0.7-4.0	K/uL
% Granulocytes	43-77	%
Absolute Granulocytes	1.7-7.7	K/uL
% Eosinophils	0-5	%
Absolute Eosinophils	0.0-0.7	K/uL
% Basophils	0-1	%
Absolute Basophils	0.0-0.1	K/uL
Erythrocyte Sedimentation Rate	Males: 0-16 Females: 0-22	mm/hr
Retic	0.4-3.1	%

Document History

02/14/07: Urines section - added reference ranges for Urine Creatinine and Urine Protein

04/11/07: Chemistries – added reference ranges for Intact Parathyroid Hormone (PTH)

04/18/07: Urines – added pediatric urine protein/creatinine levels

05/18/07: Therapeutic Drugs - added Vancomycin Trough of 15-20 ug/mL

07/03/07: Therapeutic Drugs - changed Vancomycin Trough to 5 – 20 ug/mL and added Wellmont Vancomycin Trough of 5 – 15 ug/mL

07/23/07: Chemistries – Added new Amylase value range for Federal Drive and kept value for Hospitals and Remote Sites

08/21/07: Coagulation – Added separate PT reference range for Remote Sites; INR remains the same. Chemistries – Changed Lipase to show reference range for Beckmans and Olympus.

09/17/07: Chemistries - Added Site Specific reference range for Troponin I.

11/1/07: Hematology reference ranges revised

02/28/08: Changed Hematology values back to previous ranges, prior to Nov 1 revision.

12/9/08: The following analyte reference ranges were corrected / updated:

- Indirect Bilirubin 0.3 – 0.9 corrected to 0.0 – 0.9 mg/dL
- LDL Direct < 110 corrected to AIP III classification range
- Hemoglobin A1c 4.6 – 6.5 corrected to 4.6 – 6.1 %
- Homocysteine 5.0 – 13.9 corrected to 4.0 – 15.4 umol/L
- Iron 42 – 165 corrected to gender specific ranges
- Cyclosporine 150 – 350 corrected to 140 – 330 ng/mL
- TSH 0.400 – 5.500 corrected to 0.350 – 5.500 uIU/mL
- T4 4.5 – 12.5 corrected to 5.0 – 12.5 ug/dL
- Fibrinogen 204 – 474 corrected to 204 – 475 mg/dL
- Protein C functional 91 – 147 corrected to 75 – 133 %
- Protein S functional 81 – 180 corrected to 69 – 129 %
- ATIII 75 – 125 corrected to 76 – 126 %
- C reactive protein 0.4 – 0.8 corrected to < 0.6 mg/dL
- C reactive protein high sensitivity < 0.744 corrected to low, average and high risk levels
- Factor 2 81 – 115 corrected to 74 – 131 %
- Factor 8 57 – 124 corrected to 73 – 140 %
- Factor 9 53 – 150 corrected to 75 – 134 %
- Factor 10 54 – 137 corrected to 72 – 134 %
- RDW updated from 11.5 – 14.0 to 11.5 – 15.5%
- Monocytes updated from 3 – 11 to 3 – 12%
- Absolute monocytes updated from 0.2 – 0.7 to 0.1 – 1.0
- Absolute lymphocytes updated from 0.7 – 3.3 to 0.7 – 4.0
- Absolute eosinophils updated from 0.0 – 0.7 to 0.2 – 0.7
- T3 Total updated from 60.0 – 181.0 to 80.0 – 204.0 ng/dL

Pediatric reference ranges (< 18 yrs old) were removed from the document and will be made available per request. Hospital and remote site specific analytes and reference ranges were removed from the document.

1/5/09: Updated Absolute eosinophils from 0.2 – 1.2 to 0.0 – 1.2. Updated Uric Acid to provide gender specific ranges.

12/21/09: Corrected Folate deficient range from 0.4 – 3.4 ng/mL to 0.4 – 3.3 ng/mL. Updated Vancomycin Trough reference range from 5 – 20 ug/mL to 10-20 ug/mL. Updated TSH reference range from 0.350 – 5.500 uIU/mL to 0.350 – 4.500 uIU/mL. Corrected Rubella Not Immune from ≤ 5.0 to < 5.0 IU/mL, Equivocal range from 5.1 – 9.99 to 5.0 – 9.99 IU/mL and Immune range from > 10 to ≥ 10.0 IU/mL.

12/30/10: Reformatted document. Added Carilion name. No changes to content required.



Laboratory Accreditation

Accredited
Laboratory



The College of American Pathologists

certifies that the laboratory named below

***Solstas Lab-Federal Drive
Laboratory
Greensboro, North Carolina
Janice J. Hessling, MD, PhD***

LAP Number: 6870901

AU-ID: 1191354

CLIA Number: 34D0932172

*has met all applicable standards for accreditation and
is hereby fully accredited by the College of American Pathologists'
Laboratory Accreditation Program. Reinspection should occur prior
to July 1, 2013 to maintain accreditation.*

Accreditation does not automatically survive a change in director, ownership,
or location and assumes that all interim requirements are met.

Frank R Rudy

Chair, Commission on Laboratory Accreditation

Stephen H Baum MD FACP

President, College of American Pathologists



Advancing Excellence

Accredited
Laboratory



The College of American Pathologists

certifies that the laboratory named below

Spectrum Laboratory Network

Federal Drive Location

Greensboro, North Carolina

Janice J. Hessling, MD, PhD

LAP Number: 6870901

AU-ID: 1191354

CLIA Number: 34D0932172

*has met all applicable standards for accreditation and
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Chair, Commission on Laboratory Accreditation

President, College of American Pathologists

**CENTERS FOR MEDICARE & MEDICAID SERVICES
CLINICAL LABORATORY IMPROVEMENT AMENDMENTS
CERTIFICATE OF ACCREDITATION**

LABORATORY NAME AND ADDRESS

SPECTRUM LABORATORY NETWORK-FEDERAL DR
4380 FEDERAL DRIVE STE 100
GREENSBORO, NC 27410

CLIA ID NUMBER
34D0932172

EFFECTIVE DATE
03/18/2011

LABORATORY DIRECTOR
JANICE J HESSLING MD PHD

EXPIRATION DATE
03/17/2013

Pursuant to Section 355 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

This certificate shall be valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.



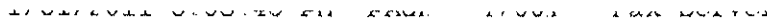
Judith A. Yost
Judith A. Yost, Director
Division of Laboratory Services
Survey and Certification Group
Center for Medicaid and State Operations

142 Certs

If you currently hold a Certificate of Compliance or Certificate of Accreditation, below is a list of the laboratory specialties/subspecialties you are certified to perform and their effective date:

<u>LAB CERTIFICATION (CODE)</u>	<u>EFFECTIVE DATE</u>	<u>LAB CERTIFICATION (CODE)</u>	<u>EFFECTIVE DATE</u>
HISTOCOMPATIBILITY (010)	11/10/2008	HISTOPATHOLOGY (610)	04/17/2008
BACTERIOLOGY (110)	03/18/1999	CYTOLOGY (630)	10/27/2000
VIROLOGY (140)	02/07/2005	CYTOGENETICS (900)	11/10/2009
SYPHILIS SEROLOGY (210)	03/18/1999		
GENERAL IMMUNOLOGY (220)	03/18/1999		
ROUTINE CHEMISTRY (310)	03/18/1999		
URINALYSIS (320)	04/03/2000		
ENDOCRINOLOGY (330)	03/18/1999		
TOXICOLOGY (340)	04/03/2000		
HEMATOLOGY (400)	03/18/1999		
ABO & RH GROUP (510)	09/21/2000		
ANTIBODY NON-TRANSFUSION (530)	09/21/2000		
ANTIBODY IDENTIFICATION (540)	01/24/2007		

FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.HHS.GOV/CLIA
OR CONTACT YOUR LOCAL STATE AGENCY. PLEASE SEE THE REVERSE FOR
YOUR STATE AGENCY'S ADDRESS AND PHONE NUMBER.
PLEASE CONTACT YOUR STATE AGENCY FOR ANY CHANGES TO YOUR CURRENT CERTIFICATE.



SOLSTASSM
LAB PARTNERS

We at Carilion-Spectrum sincerely thank you for allowing us to provide medical laboratory testing services for your practice and the patients we collectively serve.

It has been nearly a year since we announced the merger of Carilion Labs and Spectrum Laboratory Network. Since March of 2010, we have made outstanding progress toward becoming a united company and additionally, have successfully expanded our network by adding Doctors Lab, headquartered in Valdosta, GA, to our company.

Our vision for our new company has been crystal clear from the beginning. That vision has been to leverage the capabilities, experiences and resources of excellent legacy service organizations to create an even more robust new lab partner for you. I am pleased to report that we are well on our way and have many exciting enhancements in the development pipeline.

Symbolic of our integration, I am pleased to announce our new corporate name, Solstas Lab Partners. Most importantly, this name signals our passion to be your partner in providing optimal patient care during uncertain and challenging times. At its origin, "Solstas" means "turning point" and accentuates our belief that Solstas Lab Partners is the exciting new basis and turning point for our legacy companies. We now have the shared resources to expand, enhance and innovate so that we continue to be a deserving lab partner and an optimal value proposition. We are now one of the nation's top 10, full-service laboratory companies offering comprehensive clinical, anatomic pathology and esoteric testing. Servicing physicians and hospitals in 10 states with 120 patient service centers and over 3,300 skilled employees, we are well-positioned to enhance your patient's care and provide value-added services that directly benefit your practice.

Yet, we've retained many of the traits that initially attracted you to Carillon and Spectrum. Looking forward, we will strive to maintain the nimble nature of the legacy foundations to push new boundaries, respond to emerging trends and promote new technology, and stay intimate enough to remember everyone's name. You are our partner, not a number. You have my word.

While our name is new, our philosophy isn't: we will remain customer service-centric to our core, knowing that every specimen we test is the most important one.

Welcome to the new Solstas. We are just getting warmed up.

Sincerely,

David Weavil
President and CEO

16.1.11 Publications Based on the Study

No publications based on the clinical study have been written.

16.1.12 Important Publications Referenced in the Report

No publications are being submitted as an appendix to this clinical study report.
Publications cited are available upon request.

16.2 Subject Data Listings

16.2.1 Discontinued Subjects

Listing Number	Listing Title
16.2.1	Subject Disposition

Listing 16.2.1
Subject Disposition

(b) (4)



16.2.2 Protocol Deviations

Listing Number	Listing Title
16.2.2	Exclusion Tests – Drug Screen and Pregnancy

Listing 16.2.2
Exclusion Tests - Drug Screen and Pregnancy

(b) (4)



Listing 16.2.2
Exclusion Tests - Drug Screen and Pregnancy

(b) (4)



Listing 16.2.2
Exclusion Tests - Drug Screen and Pregnancy

(b) (4)



Listing 16.2.2
Exclusion Tests - Drug Screen and Pregnancy

(b) (4)



16.2.3 Demographic Data

Listing Number	Listing Title
16.2.3.1	Demographics and Screening Characteristics
16.2.3.2	Usual Brand
16.2.3.3	Medical History
16.2.3.4	Concomitant Medications
16.2.3.5	Cigarette Usage

Listing 16.2.3.1
Demographics and Screening Characteristics

Subject	Product Sequence{1}	Date Demographics Collected	Date of Birth	Age (yrs)	Gender	Race	Height (in)	Weight (lb)
01	3-2-4-1	10OCT2011	(b) (6)	43	Female	Caucasian	62	128.2
02	4-3-1-2	11OCT2011	(b) (6)	48	Male	Caucasian	70	162.8
03	2-1-3-4	10OCT2011	(b) (6)	36	Female	Caucasian	63	144
04	1-4-2-3	13OCT2011	(b) (6)	26	Male	Caucasian	74	242.4
05	3-2-4-1	14OCT2011	(b) (6)	30	Female	Caucasian	63	242.2
06	2-1-3-4	11OCT2011	(b) (6)	35	Female	Caucasian	65	267
07	4-3-1-2	13OCT2011	(b) (6)	51	Female	Caucasian	63	148.8
08	1-4-2-3	12OCT2011	(b) (6)	31	Female	Caucasian	61	227
09	4-3-1-2	17OCT2011	(b) (6)	47	Female	Caucasian	65.5	137.4
10	1-4-2-3	12OCT2011	(b) (6)	41	Female	Caucasian	64	171.4
11	2-1-3-4	17OCT2011	(b) (6)	32	Female	African American	62.5	259.8
12	3-2-4-1	18OCT2011	(b) (6)	25	Male	Caucasian	72	182.8
13	2-1-3-4	14OCT2011	(b) (6)	26	Female	Caucasian	69	134.2
14	4-3-1-2	11OCT2011	(b) (6)	35	Female	Caucasian	63	154.2
15	1-4-2-3	14OCT2011	(b) (6)	26	Male	Caucasian	69	123.2
16	3-2-4-1	13OCT2011	(b) (6)	53	Male	Caucasian	71	193.8
17	4-3-1-2	18OCT2011	(b) (6)	29	Male	Caucasian	73.5	170

{1} 1: Camel SNUS, 2: STM-1, 3: STM-2, 4: STM-3

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020301.SAS EXECUTED: 19AUG2012 15:39

Listing 16.2.3.2
Usual Brand

Subject	Product Sequence{1}	Age/Sex/ Race	Usual Brand Name	Length	Packing	Type	Filter Type	Number of cigarettes the subject typically smokes per day	Length of time subject has smoked (in years)
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(b) (4)



Listing 16.2.3.2
Usual Brand

Subject	Product Sequence{1}	Age/Sex/ Race	Usual Brand Name	Length	Packing	Type	Filter Type	Number of cigarettes the subject typically smokes per day	Length of time subject has smoked (in years)
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(b) (4)



Listing 16.2.3.3
Medical History

(b) (4)



Listing 16.2.3.3
Medical History

(b) (4)



Listing 16.2.3.3
Medical History

(b) (4)



Listing 16.2.3.3
Medical History

(b) (4)



Listing 16.2.3.4
Concomitant Medications

(b) (4)



Listing 16.2.3.4
Concomitant Medications

(b) (4)



Listing 16.2.3.4
Concomitant Medications

(b) (4)



Listing 16.2.3.5
Cigarette Usage

(b) (4)



Listing 16.2.3.5
Cigarette Usage

(b) (4)



Listing 16.2.3.5
Cigarette Usage

(b) (4)



Listing 16.2.3.5
Cigarette Usage

(b) (4)



Listing 16.2.3.5
Cigarette Usage

(b) (4)



Listing 16.2.3.5
Cigarette Usage

(b) (4)



Listing 16.2.3.5
Cigarette Usage

(b) (4)



Listing 16.2.3.5
Cigarette Usage

(b) (4)



Listing 16.2.3.5
Cigarette Usage

(b) (4)



Listing 16.2.3.5
Cigarette Usage

(b) (4)



Listing 16.2.3.5
Cigarette Usage

(b) (4)



Listing 16.2.3.5
Cigarette Usage

(b) (4)



Listing 16.2.3.5
Cigarette Usage

(b) (4)



Listing 16.2.3.5
Cigarette Usage

(b) (4)



Listing 16.2.3.5
Cigarette Usage

(b) (4)



Listing 16.2.3.5
Cigarette Usage

(b) (4)



Listing 16.2.3.5
Cigarette Usage

(b) (4)



Listing 16.2.3.5
Cigarette Usage

(b) (4)



Listing 16.2.3.5
Cigarette Usage

(b) (4)



Listing 16.2.3.5
Cigarette Usage

(b) (4)



Listing 16.2.3.5
Cigarette Usage

(b) (4)



Listing 16.2.3.5
Cigarette Usage

(b) (4)



Listing 16.2.3.5
Cigarette Usage

(b) (4)



Listing 16.2.3.5
Cigarette Usage

(b) (4)



Listing 16.2.3.5
Cigarette Usage

(b) (4)



Listing 16.2.3.5
Cigarette Usage

(b) (4)



Listing 16.2.3.5
Cigarette Usage

(b) (4)



Listing 16.2.3.5
Cigarette Usage

(b) (4)



Listing 16.2.3.5
Cigarette Usage

(b) (4)



Listing 16.2.3.5
Cigarette Usage

(b) (4)



16.2.4 Subjects Excluded from the Statistical Analysis

All available data from all enrolled and randomized subjects (N=17) were included in analyses of nicotine uptake and tobacco abstinence symptoms.

16.2.5 Compliance and/or Biomarker Concentration Data

Listing Number	Listing Title
16.2.5.1	Serum Concentrations
16.2.5.2	Derived Nicotine Uptake Parameter Estimates
16.2.5.3	Product Administration
16.2.5.4	Study Product Sampling

Listing 16.2.5.1
Serum Concentrations

Subject	Age/Sex/ Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units
01	43/F/Ca	Subject-specific, UB Cigarette	COTININE	31OCT2011/09:11:18	PRE-ADMINISTRATION	94.6	ng/mL
				31OCT2011/09:12:40	0 MINUTES POST-ADMINISTRATION	93.9	ng/mL
				31OCT2011/09:15:43	3 MINUTES POST-ADMINISTRATION	100	ng/mL
				31OCT2011/09:17:44	5 MINUTES POST-ADMINISTRATION	96.5	ng/mL
				31OCT2011/09:20:32	7.5 MINUTES POST-ADMINISTRATION	98.7	ng/mL
				31OCT2011/09:22:43	10 MINUTES POST-ADMINISTRATION	99.1	ng/mL
				31OCT2011/09:27:42	15 MINUTES POST-ADMINISTRATION	115	ng/mL
				31OCT2011/09:32:42	20 MINUTES POST-ADMINISTRATION	115	ng/mL
				31OCT2011/09:42:42	30 MINUTES POST-ADMINISTRATION	112	ng/mL
				31OCT2011/09:57:43	45 MINUTES POST-ADMINISTRATION	114	ng/mL
				31OCT2011/10:12:42	60 MINUTES POST-ADMINISTRATION	124	ng/mL
				31OCT2011/10:27:43	75 MINUTES POST-ADMINISTRATION	120	ng/mL
				31OCT2011/10:42:44	90 MINUTES POST-ADMINISTRATION	124	ng/mL
				31OCT2011/11:12:41	120 MINUTES POST-ADMINISTRATION	115	ng/mL
				31OCT2011/11:42:40	150 MINUTES POST-ADMINISTRATION	121	ng/mL
				31OCT2011/12:12:40	180 MINUTES POST-ADMINISTRATION	111	ng/mL
			NICOTINE	31OCT2011/09:11:18	PRE-ADMINISTRATION	0.558	ng/mL
				31OCT2011/09:12:40	0 MINUTES POST-ADMINISTRATION	2.48	ng/mL
				31OCT2011/09:15:43	3 MINUTES POST-ADMINISTRATION	11.8	ng/mL
				31OCT2011/09:17:44	5 MINUTES POST-ADMINISTRATION	15.1	ng/mL
				31OCT2011/09:20:32	7.5 MINUTES POST-ADMINISTRATION	21.9	ng/mL
				31OCT2011/09:22:43	10 MINUTES POST-ADMINISTRATION	21.5	ng/mL
				31OCT2011/09:27:42	15 MINUTES POST-ADMINISTRATION	18	ng/mL
				31OCT2011/09:32:42	20 MINUTES POST-ADMINISTRATION	16.6	ng/mL
				31OCT2011/09:42:42	30 MINUTES POST-ADMINISTRATION	13.6	ng/mL
				31OCT2011/09:57:43	45 MINUTES POST-ADMINISTRATION	9.79	ng/mL
				31OCT2011/10:12:42	60 MINUTES POST-ADMINISTRATION	8.78	ng/mL
				31OCT2011/10:27:43	75 MINUTES POST-ADMINISTRATION	7.53	ng/mL
				31OCT2011/10:42:44	90 MINUTES POST-ADMINISTRATION	6.65	ng/mL
				31OCT2011/11:12:41	120 MINUTES POST-ADMINISTRATION	5.06	ng/mL
				31OCT2011/11:42:40	150 MINUTES POST-ADMINISTRATION	4.36	ng/mL
				31OCT2011/12:12:40	180 MINUTES POST-ADMINISTRATION	3.56	ng/mL

Listing 16.2.5.1
Serum Concentrations

Age/Sex/ Subject Race		Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units
(b) (4)							

Listing 16.2.5.1
Serum Concentrations

Age/Sex/

Collection

Concen-

(b) (4)



Listing 16.2.5.1
Serum Concentrations

Age/Sex/

Collection

Concen-

(b) (4)



Listing 16.2.5.1
Serum Concentrations

Age/Sex/

Collection

Concen-

(b) (4)



Listing 16.2.5.1
Serum Concentrations

(b) (4)



Listing 16.2.5.1
Serum Concentrations

Subject	Age/Sex/ Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units
01	43/F/Ca	Camel SNUS	COTININE	05DEC2011/08:46:49	PRE-ADMINISTRATION	114	ng/mL
				05DEC2011/08:47:28	0 MINUTES POST-ADMINISTRATION	113	ng/mL
				05DEC2011/08:50:27	3 MINUTES POST-ADMINISTRATION	111	ng/mL
				05DEC2011/08:52:27	5 MINUTES POST-ADMINISTRATION	103	ng/mL
				05DEC2011/08:54:57	7.5 MINUTES POST-ADMINISTRATION	104	ng/mL
				05DEC2011/08:57:27	10 MINUTES POST-ADMINISTRATION	111	ng/mL
				05DEC2011/09:02:27	15 MINUTES POST-ADMINISTRATION	103	ng/mL
				05DEC2011/09:07:27	20 MINUTES POST-ADMINISTRATION	110	ng/mL
				05DEC2011/09:17:28	30 MINUTES POST-ADMINISTRATION	120	ng/mL
				05DEC2011/09:32:27	45 MINUTES POST-ADMINISTRATION	110	ng/mL
				05DEC2011/09:47:27	60 MINUTES POST-ADMINISTRATION	133	ng/mL
				05DEC2011/10:02:27	75 MINUTES POST-ADMINISTRATION	132	ng/mL
				05DEC2011/10:17:27	90 MINUTES POST-ADMINISTRATION	120	ng/mL
				05DEC2011/10:47:27	120 MINUTES POST-ADMINISTRATION	124	ng/mL
				05DEC2011/11:17:27	150 MINUTES POST-ADMINISTRATION	117	ng/mL
				05DEC2011/11:47:26	180 MINUTES POST-ADMINISTRATION	120	ng/mL
			NICOTINE	05DEC2011/08:46:49	PRE-ADMINISTRATION	0.585	ng/mL
				05DEC2011/08:47:28	0 MINUTES POST-ADMINISTRATION	0.591	ng/mL
				05DEC2011/08:50:27	3 MINUTES POST-ADMINISTRATION	0.567	ng/mL
				05DEC2011/08:52:27	5 MINUTES POST-ADMINISTRATION	0.743	ng/mL
				05DEC2011/08:54:57	7.5 MINUTES POST-ADMINISTRATION	0.968	ng/mL
				05DEC2011/08:57:27	10 MINUTES POST-ADMINISTRATION	1.7	ng/mL
				05DEC2011/09:02:27	15 MINUTES POST-ADMINISTRATION	2.89	ng/mL
				05DEC2011/09:07:27	20 MINUTES POST-ADMINISTRATION	3.65	ng/mL
				05DEC2011/09:17:28	30 MINUTES POST-ADMINISTRATION	4.49	ng/mL
				05DEC2011/09:32:27	45 MINUTES POST-ADMINISTRATION	3.9	ng/mL
				05DEC2011/09:47:27	60 MINUTES POST-ADMINISTRATION	4.14	ng/mL
				05DEC2011/10:02:27	75 MINUTES POST-ADMINISTRATION	3.93	ng/mL
				05DEC2011/10:17:27	90 MINUTES POST-ADMINISTRATION	3.29	ng/mL
				05DEC2011/10:47:27	120 MINUTES POST-ADMINISTRATION	2.62	ng/mL
				05DEC2011/11:17:27	150 MINUTES POST-ADMINISTRATION	2.12	ng/mL
				05DEC2011/11:47:26	180 MINUTES POST-ADMINISTRATION	1.82	ng/mL

Listing 16.2.5.1
Serum Concentrations

Age/Sex/ Subject Race Product			Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units
01	43/F/Ca	Camel SNUS	NICOTINE ADJ	05DEC2011/08:47:28	0 MINUTES POST-ADMINISTRATION	0.000	ng/mL
				05DEC2011/08:50:27	3 MINUTES POST-ADMINISTRATION	0.000	ng/mL
				05DEC2011/08:52:27	5 MINUTES POST-ADMINISTRATION	0.169	ng/mL
				05DEC2011/08:54:57	7.5 MINUTES POST-ADMINISTRATION	0.402	ng/mL
				05DEC2011/08:57:27	10 MINUTES POST-ADMINISTRATION	1.142	ng/mL
				05DEC2011/09:02:27	15 MINUTES POST-ADMINISTRATION	2.348	ng/mL
				05DEC2011/09:07:27	20 MINUTES POST-ADMINISTRATION	3.123	ng/mL
				05DEC2011/09:17:28	30 MINUTES POST-ADMINISTRATION	3.993	ng/mL
				05DEC2011/09:32:27	45 MINUTES POST-ADMINISTRATION	3.444	ng/mL
				05DEC2011/09:47:27	60 MINUTES POST-ADMINISTRATION	3.722	ng/mL
				05DEC2011/10:02:27	75 MINUTES POST-ADMINISTRATION	3.547	ng/mL
				05DEC2011/10:17:27	90 MINUTES POST-ADMINISTRATION	2.939	ng/mL
				05DEC2011/10:47:27	120 MINUTES POST-ADMINISTRATION	2.325	ng/mL
				05DEC2011/11:17:27	150 MINUTES POST-ADMINISTRATION	1.872	ng/mL
				05DEC2011/11:47:26	180 MINUTES POST-ADMINISTRATION	1.611	ng/mL

Listing 16.2.5.1
Serum Concentrations

Age/Sex/ Subject Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units	
02	48/M/Ca	Subject-specific, UB Cigarette	COTININE	31OCT2011/08:59:56	PRE-ADMINISTRATION	98.4	ng/mL
				31OCT2011/09:01:05	0 MINUTES POST-ADMINISTRATION	98.7	ng/mL
				31OCT2011/09:04:05	3 MINUTES POST-ADMINISTRATION	102	ng/mL
				31OCT2011/09:06:03	5 MINUTES POST-ADMINISTRATION	104	ng/mL
				31OCT2011/09:08:33	7.5 MINUTES POST-ADMINISTRATION	111	ng/mL
				31OCT2011/09:11:03	10 MINUTES POST-ADMINISTRATION	103	ng/mL
				31OCT2011/09:16:02	15 MINUTES POST-ADMINISTRATION	105	ng/mL
				31OCT2011/09:21:01	20 MINUTES POST-ADMINISTRATION	109	ng/mL
				31OCT2011/09:31:01	30 MINUTES POST-ADMINISTRATION	115	ng/mL
				31OCT2011/09:46:01	45 MINUTES POST-ADMINISTRATION	109	ng/mL
				31OCT2011/10:01:01	60 MINUTES POST-ADMINISTRATION	111	ng/mL
				31OCT2011/10:16:02	75 MINUTES POST-ADMINISTRATION	102	ng/mL
				31OCT2011/10:31:01	90 MINUTES POST-ADMINISTRATION	106	ng/mL
				31OCT2011/11:01:01	120 MINUTES POST-ADMINISTRATION	104	ng/mL
				31OCT2011/11:31:01	150 MINUTES POST-ADMINISTRATION	108	ng/mL
				31OCT2011/12:01:01	180 MINUTES POST-ADMINISTRATION	102	ng/mL

Listing 16.2.5.1
Serum Concentrations

Age/Sex/ Subject Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units	
02	48/M/Ca	Subject-specific, UB Cigarette	NICOTINE	31OCT2011/08:59:56	PRE-ADMINISTRATION	BLQ<(0.500)	ng/mL
				31OCT2011/09:01:05	0 MINUTES POST-ADMINISTRATION	BLQ<(0.500)	ng/mL
				31OCT2011/09:04:05	3 MINUTES POST-ADMINISTRATION	8.28	ng/mL
				31OCT2011/09:06:03	5 MINUTES POST-ADMINISTRATION	17	ng/mL
				31OCT2011/09:08:33	7.5 MINUTES POST-ADMINISTRATION	19.9	ng/mL
				31OCT2011/09:11:03	10 MINUTES POST-ADMINISTRATION	13	ng/mL
				31OCT2011/09:16:02	15 MINUTES POST-ADMINISTRATION	10.1	ng/mL
				31OCT2011/09:21:01	20 MINUTES POST-ADMINISTRATION	7.88	ng/mL
				31OCT2011/09:31:01	30 MINUTES POST-ADMINISTRATION	6.76	ng/mL
				31OCT2011/09:46:01	45 MINUTES POST-ADMINISTRATION	4.82	ng/mL
				31OCT2011/10:01:01	60 MINUTES POST-ADMINISTRATION	4.32	ng/mL
				31OCT2011/10:16:02	75 MINUTES POST-ADMINISTRATION	3.39	ng/mL
				31OCT2011/10:31:01	90 MINUTES POST-ADMINISTRATION	3.37	ng/mL
				31OCT2011/11:01:01	120 MINUTES POST-ADMINISTRATION	2.67	ng/mL
				31OCT2011/11:31:01	150 MINUTES POST-ADMINISTRATION	2.36	ng/mL
				31OCT2011/12:01:01	180 MINUTES POST-ADMINISTRATION	1.9	ng/mL
		NICOTINE ADJ	31OCT2011/09:01:05	0 MINUTES POST-ADMINISTRATION	0.000	ng/mL	
			31OCT2011/09:04:05	3 MINUTES POST-ADMINISTRATION	8.034	ng/mL	
			31OCT2011/09:06:03	5 MINUTES POST-ADMINISTRATION	16.757	ng/mL	
			31OCT2011/09:08:33	7.5 MINUTES POST-ADMINISTRATION	19.661	ng/mL	
			31OCT2011/09:11:03	10 MINUTES POST-ADMINISTRATION	12.764	ng/mL	
			31OCT2011/09:16:02	15 MINUTES POST-ADMINISTRATION	9.871	ng/mL	
			31OCT2011/09:21:01	20 MINUTES POST-ADMINISTRATION	7.657	ng/mL	
			31OCT2011/09:31:01	30 MINUTES POST-ADMINISTRATION	6.550	ng/mL	
			31OCT2011/09:46:01	45 MINUTES POST-ADMINISTRATION	4.627	ng/mL	
			31OCT2011/10:01:01	60 MINUTES POST-ADMINISTRATION	4.143	ng/mL	
			31OCT2011/10:16:02	75 MINUTES POST-ADMINISTRATION	3.228	ng/mL	
			31OCT2011/10:31:01	90 MINUTES POST-ADMINISTRATION	3.221	ng/mL	
			31OCT2011/11:01:01	120 MINUTES POST-ADMINISTRATION	2.545	ng/mL	
			31OCT2011/11:31:01	150 MINUTES POST-ADMINISTRATION	2.255	ng/mL	
			31OCT2011/12:01:01	180 MINUTES POST-ADMINISTRATION	1.812	ng/mL	

Listing 16.2.5.1
Serum Concentrations

(b) (4)



Listing 16.2.5.1
Serum Concentrations

(b) (4)



Listing 16.2.5.1
Serum Concentrations

(b) (4)



Listing 16.2.5.1
Serum Concentrations

Subject	Age/Sex/ Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units
02	48/M/Ca	Camel SNUS	COTININE	28NOV2011/08:50:42	PRE-ADMINISTRATION	116	ng/mL
				28NOV2011/08:51:07	0 MINUTES POST-ADMINISTRATION	114	ng/mL
				28NOV2011/08:54:09	3 MINUTES POST-ADMINISTRATION	113	ng/mL
				28NOV2011/08:56:09	5 MINUTES POST-ADMINISTRATION	117	ng/mL
				28NOV2011/08:58:38	7.5 MINUTES POST-ADMINISTRATION	114	ng/mL
				28NOV2011/09:01:08	10 MINUTES POST-ADMINISTRATION	112	ng/mL
				28NOV2011/09:06:08	15 MINUTES POST-ADMINISTRATION	110	ng/mL
				28NOV2011/09:11:08	20 MINUTES POST-ADMINISTRATION	114	ng/mL
				28NOV2011/09:21:08	30 MINUTES POST-ADMINISTRATION	118	ng/mL
				28NOV2011/09:36:07	45 MINUTES POST-ADMINISTRATION	131	ng/mL
				28NOV2011/09:51:07	60 MINUTES POST-ADMINISTRATION	138	ng/mL
				28NOV2011/10:06:08	75 MINUTES POST-ADMINISTRATION	137	ng/mL
				28NOV2011/10:21:06	90 MINUTES POST-ADMINISTRATION	137	ng/mL
				28NOV2011/10:51:06	120 MINUTES POST-ADMINISTRATION	140	ng/mL
				28NOV2011/11:21:07	150 MINUTES POST-ADMINISTRATION	132	ng/mL
				28NOV2011/11:51:08	180 MINUTES POST-ADMINISTRATION	125	ng/mL
			NICOTINE	28NOV2011/08:50:42	PRE-ADMINISTRATION	0.541	ng/mL
				28NOV2011/08:51:07	0 MINUTES POST-ADMINISTRATION	0.509	ng/mL
				28NOV2011/08:54:09	3 MINUTES POST-ADMINISTRATION	1.06	ng/mL
				28NOV2011/08:56:09	5 MINUTES POST-ADMINISTRATION	1.54	ng/mL
				28NOV2011/08:58:38	7.5 MINUTES POST-ADMINISTRATION	1.9	ng/mL
				28NOV2011/09:01:08	10 MINUTES POST-ADMINISTRATION	2.24	ng/mL
				28NOV2011/09:06:08	15 MINUTES POST-ADMINISTRATION	3.33	ng/mL
				28NOV2011/09:11:08	20 MINUTES POST-ADMINISTRATION	5.44	ng/mL
				28NOV2011/09:21:08	30 MINUTES POST-ADMINISTRATION	7.89	ng/mL
				28NOV2011/09:36:07	45 MINUTES POST-ADMINISTRATION	8.87	ng/mL
				28NOV2011/09:51:07	60 MINUTES POST-ADMINISTRATION	6.96	ng/mL
				28NOV2011/10:06:08	75 MINUTES POST-ADMINISTRATION	5.7	ng/mL
				28NOV2011/10:21:06	90 MINUTES POST-ADMINISTRATION	4.6	ng/mL
				28NOV2011/10:51:06	120 MINUTES POST-ADMINISTRATION	3.53	ng/mL
				28NOV2011/11:21:07	150 MINUTES POST-ADMINISTRATION	2.61	ng/mL
				28NOV2011/11:51:08	180 MINUTES POST-ADMINISTRATION	2.45	ng/mL

Listing 16.2.5.1
Serum Concentrations

Subject	Age/Sex/ Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units
02	48/M/Ca	Camel SNUS	NICOTINE ADJ	28NOV2011/08:51:07	0 MINUTES POST-ADMINISTRATION	0.000	ng/mL
				28NOV2011/08:54:09	3 MINUTES POST-ADMINISTRATION	0.560	ng/mL
				28NOV2011/08:56:09	5 MINUTES POST-ADMINISTRATION	1.045	ng/mL
				28NOV2011/08:58:38	7.5 MINUTES POST-ADMINISTRATION	1.413	ng/mL
				28NOV2011/09:01:08	10 MINUTES POST-ADMINISTRATION	1.760	ng/mL
				28NOV2011/09:06:08	15 MINUTES POST-ADMINISTRATION	2.863	ng/mL
				28NOV2011/09:11:08	20 MINUTES POST-ADMINISTRATION	4.987	ng/mL
				28NOV2011/09:21:08	30 MINUTES POST-ADMINISTRATION	7.462	ng/mL
				28NOV2011/09:36:07	45 MINUTES POST-ADMINISTRATION	8.478	ng/mL
				28NOV2011/09:51:07	60 MINUTES POST-ADMINISTRATION	6.600	ng/mL
				28NOV2011/10:06:08	75 MINUTES POST-ADMINISTRATION	5.370	ng/mL
				28NOV2011/10:21:06	90 MINUTES POST-ADMINISTRATION	4.297	ng/mL
				28NOV2011/10:51:06	120 MINUTES POST-ADMINISTRATION	3.276	ng/mL
				28NOV2011/11:21:07	150 MINUTES POST-ADMINISTRATION	2.396	ng/mL
				28NOV2011/11:51:08	180 MINUTES POST-ADMINISTRATION	2.270	ng/mL

(b) (4)

Listing 16.2.5.1
Serum Concentrations

(b) (4)



Listing 16.2.5.1
Serum Concentrations

Age/Sex/ Subject Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units
03	36/F/Ca	Subject-specific, UB Cigarette COTININE	31OCT2011/08:57:35	PRE-ADMINISTRATION	288	ng/mL
			31OCT2011/08:58:18	0 MINUTES POST-ADMINISTRATION	269	ng/mL
			31OCT2011/09:01:14	3 MINUTES POST-ADMINISTRATION	281	ng/mL
			31OCT2011/09:03:14	5 MINUTES POST-ADMINISTRATION	281	ng/mL
			31OCT2011/09:13:13	15 MINUTES POST-ADMINISTRATION	283	ng/mL
			31OCT2011/09:18:12	20 MINUTES POST-ADMINISTRATION	279	ng/mL
			31OCT2011/09:28:11	30 MINUTES POST-ADMINISTRATION	274	ng/mL
			31OCT2011/09:42:49	45 MINUTES POST-ADMINISTRATION	276	ng/mL
			31OCT2011/09:57:48	60 MINUTES POST-ADMINISTRATION	277	ng/mL
			31OCT2011/10:12:50	75 MINUTES POST-ADMINISTRATION	279	ng/mL
			31OCT2011/10:27:54	90 MINUTES POST-ADMINISTRATION	277	ng/mL
			31OCT2011/10:57:54	120 MINUTES POST-ADMINISTRATION	267	ng/mL
			31OCT2011/11:27:52	150 MINUTES POST-ADMINISTRATION	274	ng/mL
			31OCT2011/11:57:51	180 MINUTES POST-ADMINISTRATION	260	ng/mL
		NICOTINE	31OCT2011/08:57:35	PRE-ADMINISTRATION	3.05	ng/mL
			31OCT2011/08:58:18	0 MINUTES POST-ADMINISTRATION	6.05	ng/mL
			31OCT2011/09:01:14	3 MINUTES POST-ADMINISTRATION	7.15	ng/mL
			31OCT2011/09:03:14	5 MINUTES POST-ADMINISTRATION	13.2	ng/mL
			31OCT2011/09:13:13	15 MINUTES POST-ADMINISTRATION	16.2	ng/mL
			31OCT2011/09:18:12	20 MINUTES POST-ADMINISTRATION	15.8	ng/mL
			31OCT2011/09:28:11	30 MINUTES POST-ADMINISTRATION	13.3	ng/mL
			31OCT2011/09:42:49	45 MINUTES POST-ADMINISTRATION	12.8	ng/mL
			31OCT2011/09:57:48	60 MINUTES POST-ADMINISTRATION	11.4	ng/mL
			31OCT2011/10:12:50	75 MINUTES POST-ADMINISTRATION	10.7	ng/mL
			31OCT2011/10:27:54	90 MINUTES POST-ADMINISTRATION	9.2	ng/mL
			31OCT2011/10:57:54	120 MINUTES POST-ADMINISTRATION	11	ng/mL
			31OCT2011/11:27:52	150 MINUTES POST-ADMINISTRATION	8.21	ng/mL
			31OCT2011/11:57:51	180 MINUTES POST-ADMINISTRATION	7	ng/mL

Listing 16.2.5.1
Serum Concentrations

Age/Sex/ Subject Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units	
03	36/F/Ca	Subject-specific, UB Cigarette	NICOTINE ADJ	31OCT2011/08:58:18	0 MINUTES POST-ADMINISTRATION	0.000	ng/mL
				31OCT2011/09:01:14	3 MINUTES POST-ADMINISTRATION	1.204	ng/mL
				31OCT2011/09:03:14	5 MINUTES POST-ADMINISTRATION	7.322	ng/mL
				31OCT2011/09:13:13	15 MINUTES POST-ADMINISTRATION	10.652	ng/mL
				31OCT2011/09:18:12	20 MINUTES POST-ADMINISTRATION	10.410	ng/mL
				31OCT2011/09:28:11	30 MINUTES POST-ADMINISTRATION	8.213	ng/mL
				31OCT2011/09:42:49	45 MINUTES POST-ADMINISTRATION	8.135	ng/mL
				31OCT2011/09:57:48	60 MINUTES POST-ADMINISTRATION	7.122	ng/mL
				31OCT2011/10:12:50	75 MINUTES POST-ADMINISTRATION	6.777	ng/mL
				31OCT2011/10:27:54	90 MINUTES POST-ADMINISTRATION	5.603	ng/mL
				31OCT2011/10:57:54	120 MINUTES POST-ADMINISTRATION	7.975	ng/mL
				31OCT2011/11:27:52	150 MINUTES POST-ADMINISTRATION	5.666	ng/mL
				31OCT2011/11:57:51	180 MINUTES POST-ADMINISTRATION	4.861	ng/mL

(b) (4)

Listing 16.2.5.1
Serum Concentrations

(b) (4)



Listing 16.2.5.1
Serum Concentrations

Subject	Age/Sex/ Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units
03	36/F/Ca	Camel SNUS	COTININE	14NOV2011/08:49:46	PRE-ADMINISTRATION	234	ng/mL
				14NOV2011/08:50:55	0 MINUTES POST-ADMINISTRATION	239	ng/mL
				14NOV2011/08:53:55	3 MINUTES POST-ADMINISTRATION	249	ng/mL
				14NOV2011/08:55:55	5 MINUTES POST-ADMINISTRATION	241	ng/mL
				14NOV2011/08:58:25	7.5 MINUTES POST-ADMINISTRATION	235	ng/mL
				14NOV2011/09:00:55	10 MINUTES POST-ADMINISTRATION	231	ng/mL
				14NOV2011/09:05:55	15 MINUTES POST-ADMINISTRATION	232	ng/mL
				14NOV2011/09:10:57	20 MINUTES POST-ADMINISTRATION	242	ng/mL
				14NOV2011/09:20:55	30 MINUTES POST-ADMINISTRATION	235	ng/mL
				14NOV2011/09:35:55	45 MINUTES POST-ADMINISTRATION	240	ng/mL
				14NOV2011/09:50:55	60 MINUTES POST-ADMINISTRATION	234	ng/mL
				14NOV2011/10:06:02	75 MINUTES POST-ADMINISTRATION	242	ng/mL
				14NOV2011/10:20:55	90 MINUTES POST-ADMINISTRATION	235	ng/mL
				14NOV2011/10:50:59	120 MINUTES POST-ADMINISTRATION	241	ng/mL
				14NOV2011/11:20:59	150 MINUTES POST-ADMINISTRATION	231	ng/mL
				14NOV2011/11:51:00	180 MINUTES POST-ADMINISTRATION	229	ng/mL
			NICOTINE	14NOV2011/08:49:46	PRE-ADMINISTRATION	2.48	ng/mL
				14NOV2011/08:50:55	0 MINUTES POST-ADMINISTRATION	2.11	ng/mL
				14NOV2011/08:53:55	3 MINUTES POST-ADMINISTRATION	2.51	ng/mL
				14NOV2011/08:55:55	5 MINUTES POST-ADMINISTRATION	3.04	ng/mL
				14NOV2011/08:58:25	7.5 MINUTES POST-ADMINISTRATION	2.36	ng/mL
				14NOV2011/09:00:55	10 MINUTES POST-ADMINISTRATION	2.69	ng/mL
				14NOV2011/09:05:55	15 MINUTES POST-ADMINISTRATION	3.22	ng/mL
				14NOV2011/09:10:57	20 MINUTES POST-ADMINISTRATION	4.41	ng/mL
				14NOV2011/09:20:55	30 MINUTES POST-ADMINISTRATION	4.79	ng/mL
				14NOV2011/09:35:55	45 MINUTES POST-ADMINISTRATION	5.48	ng/mL
				14NOV2011/09:50:55	60 MINUTES POST-ADMINISTRATION	5.16	ng/mL
				14NOV2011/10:06:02	75 MINUTES POST-ADMINISTRATION	5.25	ng/mL
				14NOV2011/10:20:55	90 MINUTES POST-ADMINISTRATION	4.93	ng/mL
				14NOV2011/10:50:59	120 MINUTES POST-ADMINISTRATION	4.73	ng/mL
				14NOV2011/11:20:59	150 MINUTES POST-ADMINISTRATION	4.04	ng/mL
				14NOV2011/11:51:00	180 MINUTES POST-ADMINISTRATION	3.56	ng/mL

Listing 16.2.5.1
Serum Concentrations

Subject	Age/Sex/ Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units
03	36/F/Ca	Camel SNUS	NICOTINE ADJ	14NOV2011/08:50:55	0 MINUTES POST-ADMINISTRATION	0.000	ng/mL
				14NOV2011/08:53:55	3 MINUTES POST-ADMINISTRATION	0.436	ng/mL
				14NOV2011/08:55:55	5 MINUTES POST-ADMINISTRATION	0.990	ng/mL
				14NOV2011/08:58:25	7.5 MINUTES POST-ADMINISTRATION	0.339	ng/mL
				14NOV2011/09:00:55	10 MINUTES POST-ADMINISTRATION	0.698	ng/mL
				14NOV2011/09:05:55	15 MINUTES POST-ADMINISTRATION	1.285	ng/mL
				14NOV2011/09:10:57	20 MINUTES POST-ADMINISTRATION	2.530	ng/mL
				14NOV2011/09:20:55	30 MINUTES POST-ADMINISTRATION	3.016	ng/mL
				14NOV2011/09:35:55	45 MINUTES POST-ADMINISTRATION	3.853	ng/mL
				14NOV2011/09:50:55	60 MINUTES POST-ADMINISTRATION	3.668	ng/mL
				14NOV2011/10:06:02	75 MINUTES POST-ADMINISTRATION	3.882	ng/mL
				14NOV2011/10:20:55	90 MINUTES POST-ADMINISTRATION	3.675	ng/mL
				14NOV2011/10:50:59	120 MINUTES POST-ADMINISTRATION	3.675	ng/mL
				14NOV2011/11:20:59	150 MINUTES POST-ADMINISTRATION	3.153	ng/mL
				14NOV2011/11:51:00	180 MINUTES POST-ADMINISTRATION	2.814	ng/mL

(b) (4)

Listing 16.2.5.1
Serum Concentrations

(b) (4)



Listing 16.2.5.1
Serum Concentrations

(b) (4)



Listing 16.2.5.1
Serum Concentrations

(b) (4)



Listing 16.2.5.1
Serum Concentrations

Age/Sex/ Subject Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units	
04	26/M/Ca	Subject-specific, UB Cigarette	COTININE	31OCT2011/09:06:12	PRE-ADMINISTRATION	122	ng/mL
				31OCT2011/09:06:59	0 MINUTES POST-ADMINISTRATION	123	ng/mL
				31OCT2011/09:09:32	3 MINUTES POST-ADMINISTRATION	131	ng/mL
				31OCT2011/09:11:31	5 MINUTES POST-ADMINISTRATION	123	ng/mL
				31OCT2011/09:14:29	7.5 MINUTES POST-ADMINISTRATION	124	ng/mL
				31OCT2011/09:16:32	10 MINUTES POST-ADMINISTRATION	127	ng/mL
				31OCT2011/09:21:36	15 MINUTES POST-ADMINISTRATION	136	ng/mL
				31OCT2011/09:26:42	20 MINUTES POST-ADMINISTRATION	132	ng/mL
				31OCT2011/09:37:06	30 MINUTES POST-ADMINISTRATION	130	ng/mL
				31OCT2011/09:51:45	45 MINUTES POST-ADMINISTRATION	138	ng/mL
				31OCT2011/10:07:02	60 MINUTES POST-ADMINISTRATION	133	ng/mL
				31OCT2011/10:21:30	75 MINUTES POST-ADMINISTRATION	120	ng/mL
				31OCT2011/10:36:32	90 MINUTES POST-ADMINISTRATION	128	ng/mL
				31OCT2011/11:06:19	120 MINUTES POST-ADMINISTRATION	129	ng/mL
				31OCT2011/11:36:42	150 MINUTES POST-ADMINISTRATION	129	ng/mL
				31OCT2011/12:06:43	180 MINUTES POST-ADMINISTRATION	134	ng/mL

Listing 16.2.5.1
Serum Concentrations

Age/Sex/ Subject Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units	
04	26/M/Ca	Subject-specific, UB Cigarette	NICOTINE	31OCT2011/09:06:12	PRE-ADMINISTRATION	0.681	ng/mL
				31OCT2011/09:06:59	0 MINUTES POST-ADMINISTRATION	0.602	ng/mL
				31OCT2011/09:09:32	3 MINUTES POST-ADMINISTRATION	30.2	ng/mL
				31OCT2011/09:11:31	5 MINUTES POST-ADMINISTRATION	37.7	ng/mL
				31OCT2011/09:14:29	7.5 MINUTES POST-ADMINISTRATION	21.8	ng/mL
				31OCT2011/09:16:32	10 MINUTES POST-ADMINISTRATION	18.4	ng/mL
				31OCT2011/09:21:36	15 MINUTES POST-ADMINISTRATION	14	ng/mL
				31OCT2011/09:26:42	20 MINUTES POST-ADMINISTRATION	10.6	ng/mL
				31OCT2011/09:37:06	30 MINUTES POST-ADMINISTRATION	7.71	ng/mL
				31OCT2011/09:51:45	45 MINUTES POST-ADMINISTRATION	6.54	ng/mL
				31OCT2011/10:07:02	60 MINUTES POST-ADMINISTRATION	5.76	ng/mL
				31OCT2011/10:21:30	75 MINUTES POST-ADMINISTRATION	4.07	ng/mL
				31OCT2011/10:36:32	90 MINUTES POST-ADMINISTRATION	3.64	ng/mL
				31OCT2011/11:06:19	120 MINUTES POST-ADMINISTRATION	2.5	ng/mL
				31OCT2011/11:36:42	150 MINUTES POST-ADMINISTRATION	2.56	ng/mL
				31OCT2011/12:06:43	180 MINUTES POST-ADMINISTRATION	2.4	ng/mL
		NICOTINE ADJ		31OCT2011/09:06:59	0 MINUTES POST-ADMINISTRATION	0.000	ng/mL
				31OCT2011/09:09:32	3 MINUTES POST-ADMINISTRATION	29.608	ng/mL
				31OCT2011/09:11:31	5 MINUTES POST-ADMINISTRATION	37.115	ng/mL
				31OCT2011/09:14:29	7.5 MINUTES POST-ADMINISTRATION	21.224	ng/mL
				31OCT2011/09:16:32	10 MINUTES POST-ADMINISTRATION	17.832	ng/mL
				31OCT2011/09:21:36	15 MINUTES POST-ADMINISTRATION	13.448	ng/mL
				31OCT2011/09:26:42	20 MINUTES POST-ADMINISTRATION	10.064	ng/mL
				31OCT2011/09:37:06	30 MINUTES POST-ADMINISTRATION	7.204	ng/mL
				31OCT2011/09:51:45	45 MINUTES POST-ADMINISTRATION	6.076	ng/mL
				31OCT2011/10:07:02	60 MINUTES POST-ADMINISTRATION	5.334	ng/mL
				31OCT2011/10:21:30	75 MINUTES POST-ADMINISTRATION	3.680	ng/mL
				31OCT2011/10:36:32	90 MINUTES POST-ADMINISTRATION	3.282	ng/mL
				31OCT2011/11:06:19	120 MINUTES POST-ADMINISTRATION	2.199	ng/mL
				31OCT2011/11:36:42	150 MINUTES POST-ADMINISTRATION	2.307	ng/mL
				31OCT2011/12:06:43	180 MINUTES POST-ADMINISTRATION	2.187	ng/mL

Listing 16.2.5.1
Serum Concentrations

Subject	Age/Sex/ Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units
04	26/M/Ca	Camel SNUS	COTININE	07NOV2011/08:46:36	PRE-ADMINISTRATION	166	ng/mL
				07NOV2011/08:47:35	0 MINUTES POST-ADMINISTRATION	166	ng/mL
				07NOV2011/08:50:58	3 MINUTES POST-ADMINISTRATION	164	ng/mL
				07NOV2011/08:52:35	5 MINUTES POST-ADMINISTRATION	166	ng/mL
				07NOV2011/08:55:05	7.5 MINUTES POST-ADMINISTRATION	154	ng/mL
				07NOV2011/08:57:35	10 MINUTES POST-ADMINISTRATION	160	ng/mL
				07NOV2011/09:02:55	15 MINUTES POST-ADMINISTRATION	158	ng/mL
				07NOV2011/09:07:35	20 MINUTES POST-ADMINISTRATION	168	ng/mL
				07NOV2011/09:17:55	30 MINUTES POST-ADMINISTRATION	167	ng/mL
				07NOV2011/09:33:00	45 MINUTES POST-ADMINISTRATION	178	ng/mL
				07NOV2011/09:47:30	60 MINUTES POST-ADMINISTRATION	174	ng/mL
				07NOV2011/10:02:35	75 MINUTES POST-ADMINISTRATION	177	ng/mL
				07NOV2011/10:18:01	90 MINUTES POST-ADMINISTRATION	162	ng/mL
				07NOV2011/10:47:14	120 MINUTES POST-ADMINISTRATION	156	ng/mL
				07NOV2011/11:16:50	150 MINUTES POST-ADMINISTRATION	159	ng/mL
				07NOV2011/11:48:11	180 MINUTES POST-ADMINISTRATION	163	ng/mL
			NICOTINE	07NOV2011/08:46:36	PRE-ADMINISTRATION	1.12	ng/mL
				07NOV2011/08:47:35	0 MINUTES POST-ADMINISTRATION	0.896	ng/mL
				07NOV2011/08:50:58	3 MINUTES POST-ADMINISTRATION	1.33	ng/mL
				07NOV2011/08:52:35	5 MINUTES POST-ADMINISTRATION	2.07	ng/mL
				07NOV2011/08:55:05	7.5 MINUTES POST-ADMINISTRATION	3.71	ng/mL
				07NOV2011/08:57:35	10 MINUTES POST-ADMINISTRATION	4.28	ng/mL
				07NOV2011/09:02:55	15 MINUTES POST-ADMINISTRATION	4.84	ng/mL
				07NOV2011/09:07:35	20 MINUTES POST-ADMINISTRATION	6.51	ng/mL
				07NOV2011/09:17:55	30 MINUTES POST-ADMINISTRATION	7.16	ng/mL
				07NOV2011/09:33:00	45 MINUTES POST-ADMINISTRATION	4.84	ng/mL
				07NOV2011/09:47:30	60 MINUTES POST-ADMINISTRATION	4.34	ng/mL
				07NOV2011/10:02:35	75 MINUTES POST-ADMINISTRATION	3.7	ng/mL
				07NOV2011/10:18:01	90 MINUTES POST-ADMINISTRATION	3.29	ng/mL
				07NOV2011/10:47:14	120 MINUTES POST-ADMINISTRATION	2.64	ng/mL
				07NOV2011/11:16:50	150 MINUTES POST-ADMINISTRATION	2.18	ng/mL
				07NOV2011/11:48:11	180 MINUTES POST-ADMINISTRATION	1.99	ng/mL

Listing 16.2.5.1
Serum Concentrations

Subject	Age/Sex/ Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units
04	26/M/Ca	Camel SNUS	NICOTINE ADJ	07NOV2011/08:47:35	0 MINUTES POST-ADMINISTRATION	0.000	ng/mL
				07NOV2011/08:50:58	3 MINUTES POST-ADMINISTRATION	0.449	ng/mL
				07NOV2011/08:52:35	5 MINUTES POST-ADMINISTRATION	1.200	ng/mL
				07NOV2011/08:55:05	7.5 MINUTES POST-ADMINISTRATION	2.852	ng/mL
				07NOV2011/08:57:35	10 MINUTES POST-ADMINISTRATION	3.434	ng/mL
				07NOV2011/09:02:55	15 MINUTES POST-ADMINISTRATION	4.018	ng/mL
				07NOV2011/09:07:35	20 MINUTES POST-ADMINISTRATION	5.712	ng/mL
				07NOV2011/09:17:55	30 MINUTES POST-ADMINISTRATION	6.407	ng/mL
				07NOV2011/09:33:00	45 MINUTES POST-ADMINISTRATION	4.149	ng/mL
				07NOV2011/09:47:30	60 MINUTES POST-ADMINISTRATION	3.706	ng/mL
				07NOV2011/10:02:35	75 MINUTES POST-ADMINISTRATION	3.119	ng/mL
				07NOV2011/10:18:01	90 MINUTES POST-ADMINISTRATION	2.757	ng/mL
				07NOV2011/10:47:14	120 MINUTES POST-ADMINISTRATION	2.192	ng/mL
				07NOV2011/11:16:50	150 MINUTES POST-ADMINISTRATION	1.803	ng/mL
				07NOV2011/11:48:11	180 MINUTES POST-ADMINISTRATION	1.673	ng/mL

(b) (4)

Listing 16.2.5.1
Serum Concentrations

(b) (4)



Listing 16.2.5.1
Serum Concentrations

(b) (4)



Listing 16.2.5.1
Serum Concentrations

(b) (4)



Listing 16.2.5.1
Serum Concentrations

(b) (4)



Listing 16.2.5.1
Serum Concentrations

Age/Sex/ Subject Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units	
05	30/F/Ca	Subject-specific, UB Cigarette	COTININE	01NOV2011/09:07:45	PRE-ADMINISTRATION	186	ng/mL
				01NOV2011/09:08:58	0 MINUTES POST-ADMINISTRATION	181	ng/mL
				01NOV2011/09:11:57	3 MINUTES POST-ADMINISTRATION	193	ng/mL
				01NOV2011/09:13:57	5 MINUTES POST-ADMINISTRATION	179	ng/mL
				01NOV2011/09:16:27	7.5 MINUTES POST-ADMINISTRATION	180	ng/mL
				01NOV2011/09:18:58	10 MINUTES POST-ADMINISTRATION	182	ng/mL
				01NOV2011/09:23:58	15 MINUTES POST-ADMINISTRATION	175	ng/mL
				01NOV2011/09:28:58	20 MINUTES POST-ADMINISTRATION	185	ng/mL
				01NOV2011/09:38:57	30 MINUTES POST-ADMINISTRATION	180	ng/mL
				01NOV2011/09:53:56	45 MINUTES POST-ADMINISTRATION	187	ng/mL
				01NOV2011/10:08:56	60 MINUTES POST-ADMINISTRATION	182	ng/mL
				01NOV2011/10:23:56	75 MINUTES POST-ADMINISTRATION	192	ng/mL
				01NOV2011/10:38:55	90 MINUTES POST-ADMINISTRATION	170	ng/mL
				01NOV2011/11:07:54	120 MINUTES POST-ADMINISTRATION	164	ng/mL
				01NOV2011/11:37:54	150 MINUTES POST-ADMINISTRATION	164	ng/mL
				01NOV2011/12:07:52	180 MINUTES POST-ADMINISTRATION	165	ng/mL
		NICOTINE	NICOTINE	01NOV2011/09:07:45	PRE-ADMINISTRATION	1.2	ng/mL
				01NOV2011/09:08:58	0 MINUTES POST-ADMINISTRATION	1.13	ng/mL
				01NOV2011/09:11:57	3 MINUTES POST-ADMINISTRATION	12.5	ng/mL
				01NOV2011/09:13:57	5 MINUTES POST-ADMINISTRATION	15.5	ng/mL
				01NOV2011/09:16:27	7.5 MINUTES POST-ADMINISTRATION	16	ng/mL
				01NOV2011/09:18:58	10 MINUTES POST-ADMINISTRATION	12.2	ng/mL
				01NOV2011/09:23:58	15 MINUTES POST-ADMINISTRATION	10.6	ng/mL
				01NOV2011/09:28:58	20 MINUTES POST-ADMINISTRATION	7.8	ng/mL
				01NOV2011/09:38:57	30 MINUTES POST-ADMINISTRATION	6.7	ng/mL
				01NOV2011/09:53:56	45 MINUTES POST-ADMINISTRATION	6.09	ng/mL
				01NOV2011/10:08:56	60 MINUTES POST-ADMINISTRATION	5.25	ng/mL
				01NOV2011/10:23:56	75 MINUTES POST-ADMINISTRATION	4.78	ng/mL
				01NOV2011/10:38:55	90 MINUTES POST-ADMINISTRATION	4.04	ng/mL
				01NOV2011/11:07:54	120 MINUTES POST-ADMINISTRATION	3.64	ng/mL
				01NOV2011/11:37:54	150 MINUTES POST-ADMINISTRATION	3.26	ng/mL
				01NOV2011/12:07:52	180 MINUTES POST-ADMINISTRATION	2.84	ng/mL

Listing 16.2.5.1
Serum Concentrations

Age/Sex/ Subject Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units	
05	30/F/Ca	Subject-specific, UB Cigarette	NICOTINE ADJ	01NOV2011/09:08:58	0 MINUTES POST-ADMINISTRATION	0.000	ng/mL
				01NOV2011/09:11:57	3 MINUTES POST-ADMINISTRATION	11.389	ng/mL
				01NOV2011/09:13:57	5 MINUTES POST-ADMINISTRATION	14.402	ng/mL
				01NOV2011/09:16:27	7.5 MINUTES POST-ADMINISTRATION	14.918	ng/mL
				01NOV2011/09:18:58	10 MINUTES POST-ADMINISTRATION	11.133	ng/mL
				01NOV2011/09:23:58	15 MINUTES POST-ADMINISTRATION	9.564	ng/mL
				01NOV2011/09:28:58	20 MINUTES POST-ADMINISTRATION	6.793	ng/mL
				01NOV2011/09:38:57	30 MINUTES POST-ADMINISTRATION	5.750	ng/mL
				01NOV2011/09:53:56	45 MINUTES POST-ADMINISTRATION	5.219	ng/mL
				01NOV2011/10:08:56	60 MINUTES POST-ADMINISTRATION	4.451	ng/mL
				01NOV2011/10:23:56	75 MINUTES POST-ADMINISTRATION	4.047	ng/mL
				01NOV2011/10:38:55	90 MINUTES POST-ADMINISTRATION	3.368	ng/mL
				01NOV2011/11:07:54	120 MINUTES POST-ADMINISTRATION	3.075	ng/mL
				01NOV2011/11:37:54	150 MINUTES POST-ADMINISTRATION	2.785	ng/mL
				01NOV2011/12:07:52	180 MINUTES POST-ADMINISTRATION	2.440	ng/mL

(b) (4)

Listing 16.2.5.1
Serum Concentrations

(b) (4)



Listing 16.2.5.1
Serum Concentrations

(b) (4)



Listing 16.2.5.1
Serum Concentrations

(b) (4)



Listing 16.2.5.1
Serum Concentrations

(b) (4)



Listing 16.2.5.1
Serum Concentrations

Subject	Age/Sex/ Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units
05	30/F/Ca	Camel SNUS	COTININE	06DEC2011/08:41:42	PRE-ADMINISTRATION	177	ng/mL
				06DEC2011/08:42:24	0 MINUTES POST-ADMINISTRATION	173	ng/mL
				06DEC2011/08:45:23	3 MINUTES POST-ADMINISTRATION	175	ng/mL
				06DEC2011/08:47:23	5 MINUTES POST-ADMINISTRATION	173	ng/mL
				06DEC2011/08:50:05	7.5 MINUTES POST-ADMINISTRATION	166	ng/mL
				06DEC2011/08:52:22	10 MINUTES POST-ADMINISTRATION	171	ng/mL
				06DEC2011/08:57:23	15 MINUTES POST-ADMINISTRATION	175	ng/mL
				06DEC2011/09:02:23	20 MINUTES POST-ADMINISTRATION	172	ng/mL
				06DEC2011/09:12:23	30 MINUTES POST-ADMINISTRATION	174	ng/mL
				06DEC2011/09:27:22	45 MINUTES POST-ADMINISTRATION	173	ng/mL
				06DEC2011/09:42:23	60 MINUTES POST-ADMINISTRATION	180	ng/mL
				06DEC2011/09:57:22	75 MINUTES POST-ADMINISTRATION	166	ng/mL
				06DEC2011/10:12:24	90 MINUTES POST-ADMINISTRATION	168	ng/mL
				06DEC2011/10:42:22	120 MINUTES POST-ADMINISTRATION	168	ng/mL
				06DEC2011/11:12:22	150 MINUTES POST-ADMINISTRATION	164	ng/mL
				06DEC2011/11:42:23	180 MINUTES POST-ADMINISTRATION	161	ng/mL
			NICOTINE	06DEC2011/08:41:42	PRE-ADMINISTRATION	1.14	ng/mL
				06DEC2011/08:42:24	0 MINUTES POST-ADMINISTRATION	1.12	ng/mL
				06DEC2011/08:45:23	3 MINUTES POST-ADMINISTRATION	1.11	ng/mL
				06DEC2011/08:47:23	5 MINUTES POST-ADMINISTRATION	1.37	ng/mL
				06DEC2011/08:50:05	7.5 MINUTES POST-ADMINISTRATION	1.81	ng/mL
				06DEC2011/08:52:22	10 MINUTES POST-ADMINISTRATION	1.9	ng/mL
				06DEC2011/08:57:23	15 MINUTES POST-ADMINISTRATION	2.81	ng/mL
				06DEC2011/09:02:23	20 MINUTES POST-ADMINISTRATION	2.74	ng/mL
				06DEC2011/09:12:23	30 MINUTES POST-ADMINISTRATION	2.87	ng/mL
				06DEC2011/09:27:22	45 MINUTES POST-ADMINISTRATION	3.12	ng/mL
				06DEC2011/09:42:23	60 MINUTES POST-ADMINISTRATION	2.97	ng/mL
				06DEC2011/09:57:22	75 MINUTES POST-ADMINISTRATION	2.55	ng/mL
				06DEC2011/10:12:24	90 MINUTES POST-ADMINISTRATION	2.49	ng/mL
				06DEC2011/10:42:22	120 MINUTES POST-ADMINISTRATION	2.52	ng/mL
				06DEC2011/11:12:22	150 MINUTES POST-ADMINISTRATION	2.32	ng/mL
				06DEC2011/11:42:23	180 MINUTES POST-ADMINISTRATION	1.87	ng/mL

Listing 16.2.5.1
Serum Concentrations

Age/Sex/ Subject Race			Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units
05	30/F/Ca	Camel SNUS	NICOTINE ADJ	06DEC2011/08:42:24	0 MINUTES POST-ADMINISTRATION	0.000	ng/mL	
				06DEC2011/08:45:23	3 MINUTES POST-ADMINISTRATION	0.009	ng/mL	
				06DEC2011/08:47:23	5 MINUTES POST-ADMINISTRATION	0.282	ng/mL	
				06DEC2011/08:50:05	7.5 MINUTES POST-ADMINISTRATION	0.737	ng/mL	
				06DEC2011/08:52:22	10 MINUTES POST-ADMINISTRATION	0.843	ng/mL	
				06DEC2011/08:57:23	15 MINUTES POST-ADMINISTRATION	1.783	ng/mL	
				06DEC2011/09:02:23	20 MINUTES POST-ADMINISTRATION	1.742	ng/mL	
				06DEC2011/09:12:23	30 MINUTES POST-ADMINISTRATION	1.928	ng/mL	
				06DEC2011/09:27:22	45 MINUTES POST-ADMINISTRATION	2.256	ng/mL	
				06DEC2011/09:42:23	60 MINUTES POST-ADMINISTRATION	2.178	ng/mL	
				06DEC2011/09:57:22	75 MINUTES POST-ADMINISTRATION	1.824	ng/mL	
				06DEC2011/10:12:24	90 MINUTES POST-ADMINISTRATION	1.824	ng/mL	
				06DEC2011/10:42:22	120 MINUTES POST-ADMINISTRATION	1.960	ng/mL	
				06DEC2011/11:12:22	150 MINUTES POST-ADMINISTRATION	1.849	ng/mL	
				06DEC2011/11:42:23	180 MINUTES POST-ADMINISTRATION	1.474	ng/mL	

Listing 16.2.5.1
Serum Concentrations

Age/Sex/ Subject Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units	
06	35/F/Ca	Subject-specific, UB Cigarette	COTININE	01NOV2011/09:08:42	PRE-ADMINISTRATION	108	ng/mL
				01NOV2011/09:09:34	0 MINUTES POST-ADMINISTRATION	109	ng/mL
				01NOV2011/09:12:44	3 MINUTES POST-ADMINISTRATION	108	ng/mL
				01NOV2011/09:14:32	5 MINUTES POST-ADMINISTRATION	108	ng/mL
				01NOV2011/09:17:03	7.5 MINUTES POST-ADMINISTRATION	95.7	ng/mL
				01NOV2011/09:19:34	10 MINUTES POST-ADMINISTRATION	112	ng/mL
				01NOV2011/09:24:33	15 MINUTES POST-ADMINISTRATION	108	ng/mL
				01NOV2011/09:29:34	20 MINUTES POST-ADMINISTRATION	109	ng/mL
				01NOV2011/09:39:33	30 MINUTES POST-ADMINISTRATION	109	ng/mL
				01NOV2011/09:54:32	45 MINUTES POST-ADMINISTRATION	112	ng/mL
				01NOV2011/10:09:33	60 MINUTES POST-ADMINISTRATION	108	ng/mL
				01NOV2011/10:24:32	75 MINUTES POST-ADMINISTRATION	109	ng/mL
				01NOV2011/10:39:32	90 MINUTES POST-ADMINISTRATION	108	ng/mL
				01NOV2011/11:09:32	120 MINUTES POST-ADMINISTRATION	100	ng/mL
				01NOV2011/11:39:31	150 MINUTES POST-ADMINISTRATION	97.5	ng/mL
				01NOV2011/12:10:25	180 MINUTES POST-ADMINISTRATION	96.2	ng/mL

Listing 16.2.5.1
Serum Concentrations

Age/Sex/ Subject Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units	
06	35/F/Ca	Subject-specific, UB Cigarette	NICOTINE	01NOV2011/09:08:42	PRE-ADMINISTRATION	BLQ<(0.500)	ng/mL
				01NOV2011/09:09:34	0 MINUTES POST-ADMINISTRATION	BLQ<(0.500)	ng/mL
				01NOV2011/09:12:44	3 MINUTES POST-ADMINISTRATION	2.69	ng/mL
				01NOV2011/09:14:32	5 MINUTES POST-ADMINISTRATION	4.19	ng/mL
				01NOV2011/09:17:03	7.5 MINUTES POST-ADMINISTRATION	6.31	ng/mL
				01NOV2011/09:19:34	10 MINUTES POST-ADMINISTRATION	8.35	ng/mL
				01NOV2011/09:24:33	15 MINUTES POST-ADMINISTRATION	5.57	ng/mL
				01NOV2011/09:29:34	20 MINUTES POST-ADMINISTRATION	5.28	ng/mL
				01NOV2011/09:39:33	30 MINUTES POST-ADMINISTRATION	4.28	ng/mL
				01NOV2011/09:54:32	45 MINUTES POST-ADMINISTRATION	3.95	ng/mL
				01NOV2011/10:09:33	60 MINUTES POST-ADMINISTRATION	3.39	ng/mL
				01NOV2011/10:24:32	75 MINUTES POST-ADMINISTRATION	3.28	ng/mL
				01NOV2011/10:39:32	90 MINUTES POST-ADMINISTRATION	3.33	ng/mL
				01NOV2011/11:09:32	120 MINUTES POST-ADMINISTRATION	2.57	ng/mL
				01NOV2011/11:39:31	150 MINUTES POST-ADMINISTRATION	2.24	ng/mL
				01NOV2011/12:10:25	180 MINUTES POST-ADMINISTRATION	1.66	ng/mL
		NICOTINE ADJ		01NOV2011/09:09:34	0 MINUTES POST-ADMINISTRATION	0.000	ng/mL
				01NOV2011/09:12:44	3 MINUTES POST-ADMINISTRATION	2.444	ng/mL
				01NOV2011/09:14:32	5 MINUTES POST-ADMINISTRATION	3.947	ng/mL
				01NOV2011/09:17:03	7.5 MINUTES POST-ADMINISTRATION	6.071	ng/mL
				01NOV2011/09:19:34	10 MINUTES POST-ADMINISTRATION	8.114	ng/mL
				01NOV2011/09:24:33	15 MINUTES POST-ADMINISTRATION	5.341	ng/mL
				01NOV2011/09:29:34	20 MINUTES POST-ADMINISTRATION	5.057	ng/mL
				01NOV2011/09:39:33	30 MINUTES POST-ADMINISTRATION	4.070	ng/mL
				01NOV2011/09:54:32	45 MINUTES POST-ADMINISTRATION	3.757	ng/mL
				01NOV2011/10:09:33	60 MINUTES POST-ADMINISTRATION	3.213	ng/mL
				01NOV2011/10:24:32	75 MINUTES POST-ADMINISTRATION	3.118	ng/mL
				01NOV2011/10:39:32	90 MINUTES POST-ADMINISTRATION	3.181	ng/mL
				01NOV2011/11:09:32	120 MINUTES POST-ADMINISTRATION	2.445	ng/mL
				01NOV2011/11:39:31	150 MINUTES POST-ADMINISTRATION	2.135	ng/mL
				01NOV2011/12:10:25	180 MINUTES POST-ADMINISTRATION	1.572	ng/mL

Listing 16.2.5.1
Serum Concentrations

(b) (4)



Listing 16.2.5.1
Serum Concentrations

(b) (4)



Listing 16.2.5.1
Serum Concentrations

Age/Sex/ Subject Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units
06	35/F/Ca Camel SNUS	NICOTINE	15NOV2011/08:58:27	PRE-ADMINISTRATION	BLQ<(0.500)	ng/mL
			15NOV2011/08:58:56	0 MINUTES POST-ADMINISTRATION	BLQ<(0.500)	ng/mL
			15NOV2011/09:01:55	3 MINUTES POST-ADMINISTRATION	1.05	ng/mL
			15NOV2011/09:03:55	5 MINUTES POST-ADMINISTRATION	1.7	ng/mL
			15NOV2011/09:06:27	7.5 MINUTES POST-ADMINISTRATION	2.05	ng/mL
			15NOV2011/09:08:55	10 MINUTES POST-ADMINISTRATION	1.74	ng/mL
			15NOV2011/09:13:55	15 MINUTES POST-ADMINISTRATION	1.63	ng/mL
			15NOV2011/09:18:56	20 MINUTES POST-ADMINISTRATION	1.94	ng/mL
			15NOV2011/09:28:57	30 MINUTES POST-ADMINISTRATION	1.88	ng/mL
			15NOV2011/09:43:57	45 MINUTES POST-ADMINISTRATION	1.28	ng/mL
			15NOV2011/09:58:56	60 MINUTES POST-ADMINISTRATION	1.41	ng/mL
			15NOV2011/10:14:44	75 MINUTES POST-ADMINISTRATION	1.12	ng/mL
			15NOV2011/10:28:56	90 MINUTES POST-ADMINISTRATION	1.13	ng/mL
			15NOV2011/10:58:57	120 MINUTES POST-ADMINISTRATION	1.18	ng/mL
			15NOV2011/11:28:56	150 MINUTES POST-ADMINISTRATION	0.872	ng/mL
			15NOV2011/11:58:56	180 MINUTES POST-ADMINISTRATION	0.775	ng/mL
		NICOTINE ADJ	15NOV2011/08:58:56	0 MINUTES POST-ADMINISTRATION	0.000	ng/mL
			15NOV2011/09:01:55	3 MINUTES POST-ADMINISTRATION	0.804	ng/mL
			15NOV2011/09:03:55	5 MINUTES POST-ADMINISTRATION	1.457	ng/mL
			15NOV2011/09:06:27	7.5 MINUTES POST-ADMINISTRATION	1.811	ng/mL
			15NOV2011/09:08:55	10 MINUTES POST-ADMINISTRATION	1.504	ng/mL
			15NOV2011/09:13:55	15 MINUTES POST-ADMINISTRATION	1.401	ng/mL
			15NOV2011/09:18:56	20 MINUTES POST-ADMINISTRATION	1.717	ng/mL
			15NOV2011/09:28:57	30 MINUTES POST-ADMINISTRATION	1.670	ng/mL
			15NOV2011/09:43:57	45 MINUTES POST-ADMINISTRATION	1.087	ng/mL
			15NOV2011/09:58:56	60 MINUTES POST-ADMINISTRATION	1.233	ng/mL
			15NOV2011/10:14:44	75 MINUTES POST-ADMINISTRATION	0.958	ng/mL
			15NOV2011/10:28:56	90 MINUTES POST-ADMINISTRATION	0.981	ng/mL
			15NOV2011/10:58:57	120 MINUTES POST-ADMINISTRATION	1.055	ng/mL
			15NOV2011/11:28:56	150 MINUTES POST-ADMINISTRATION	0.767	ng/mL
			15NOV2011/11:58:56	180 MINUTES POST-ADMINISTRATION	0.687	ng/mL

Listing 16.2.5.1
Serum Concentrations

(b) (4)



Listing 16.2.5.1
Serum Concentrations

(b) (4)



Listing 16.2.5.1
Serum Concentrations

(b) (4)



Listing 16.2.5.1
Serum Concentrations

Age/Sex/ Subject Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units	
07	51/F/Ca	Subject-specific, UB Cigarette	COTININE	01NOV2011/09:08:49	PRE-ADMINISTRATION	92.4	ng/mL
				01NOV2011/09:10:23	0 MINUTES POST-ADMINISTRATION	91.7	ng/mL
				01NOV2011/09:13:21	3 MINUTES POST-ADMINISTRATION	89.6	ng/mL
				01NOV2011/09:15:20	5 MINUTES POST-ADMINISTRATION	90.8	ng/mL
				01NOV2011/09:17:51	7.5 MINUTES POST-ADMINISTRATION	93.5	ng/mL
				01NOV2011/09:20:20	10 MINUTES POST-ADMINISTRATION	95.8	ng/mL
				01NOV2011/09:25:21	15 MINUTES POST-ADMINISTRATION	98.2	ng/mL
				01NOV2011/09:30:21	20 MINUTES POST-ADMINISTRATION	91	ng/mL
				01NOV2011/09:40:21	30 MINUTES POST-ADMINISTRATION	99.1	ng/mL
				01NOV2011/09:55:23	45 MINUTES POST-ADMINISTRATION	104	ng/mL
				01NOV2011/10:10:22	60 MINUTES POST-ADMINISTRATION	101	ng/mL
				01NOV2011/10:25:22	75 MINUTES POST-ADMINISTRATION	100	ng/mL
				01NOV2011/10:40:21	90 MINUTES POST-ADMINISTRATION	103	ng/mL
				01NOV2011/11:10:21	120 MINUTES POST-ADMINISTRATION	94.2	ng/mL
				01NOV2011/11:40:21	150 MINUTES POST-ADMINISTRATION	88.2	ng/mL
				01NOV2011/12:10:25	180 MINUTES POST-ADMINISTRATION	85	ng/mL
		NICOTINE	NICOTINE	01NOV2011/09:08:49	PRE-ADMINISTRATION	0.911	ng/mL
				01NOV2011/09:10:23	0 MINUTES POST-ADMINISTRATION	0.573	ng/mL
				01NOV2011/09:13:21	3 MINUTES POST-ADMINISTRATION	3.48	ng/mL
				01NOV2011/09:15:20	5 MINUTES POST-ADMINISTRATION	5.65	ng/mL
				01NOV2011/09:17:51	7.5 MINUTES POST-ADMINISTRATION	9.31	ng/mL
				01NOV2011/09:20:20	10 MINUTES POST-ADMINISTRATION	10.1	ng/mL
				01NOV2011/09:25:21	15 MINUTES POST-ADMINISTRATION	9.21	ng/mL
				01NOV2011/09:30:21	20 MINUTES POST-ADMINISTRATION	7.51	ng/mL
				01NOV2011/09:40:21	30 MINUTES POST-ADMINISTRATION	6.82	ng/mL
				01NOV2011/09:55:23	45 MINUTES POST-ADMINISTRATION	5.71	ng/mL
				01NOV2011/10:10:22	60 MINUTES POST-ADMINISTRATION	5.11	ng/mL
				01NOV2011/10:25:22	75 MINUTES POST-ADMINISTRATION	4.72	ng/mL
				01NOV2011/10:40:21	90 MINUTES POST-ADMINISTRATION	4.46	ng/mL
				01NOV2011/11:10:21	120 MINUTES POST-ADMINISTRATION	3.62	ng/mL
				01NOV2011/11:40:21	150 MINUTES POST-ADMINISTRATION	3.26	ng/mL
				01NOV2011/12:10:25	180 MINUTES POST-ADMINISTRATION	2.32	ng/mL

Listing 16.2.5.1
Serum Concentrations

Age/Sex/ Subject Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units	
07	51/F/Ca	Subject-specific, UB Cigarette	NICOTINE ADJ	01NOV2011/09:10:23	0 MINUTES POST-ADMINISTRATION	0.000	ng/mL
				01NOV2011/09:13:21	3 MINUTES POST-ADMINISTRATION	2.917	ng/mL
				01NOV2011/09:15:20	5 MINUTES POST-ADMINISTRATION	5.093	ng/mL
				01NOV2011/09:17:51	7.5 MINUTES POST-ADMINISTRATION	8.761	ng/mL
				01NOV2011/09:20:20	10 MINUTES POST-ADMINISTRATION	9.559	ng/mL
				01NOV2011/09:25:21	15 MINUTES POST-ADMINISTRATION	8.685	ng/mL
				01NOV2011/09:30:21	20 MINUTES POST-ADMINISTRATION	7.000	ng/mL
				01NOV2011/09:40:21	30 MINUTES POST-ADMINISTRATION	6.338	ng/mL
				01NOV2011/09:55:23	45 MINUTES POST-ADMINISTRATION	5.268	ng/mL
				01NOV2011/10:10:22	60 MINUTES POST-ADMINISTRATION	4.705	ng/mL
				01NOV2011/10:25:22	75 MINUTES POST-ADMINISTRATION	4.348	ng/mL
				01NOV2011/10:40:21	90 MINUTES POST-ADMINISTRATION	4.119	ng/mL
				01NOV2011/11:10:21	120 MINUTES POST-ADMINISTRATION	3.334	ng/mL
				01NOV2011/11:40:21	150 MINUTES POST-ADMINISTRATION	3.019	ng/mL
				01NOV2011/12:10:25	180 MINUTES POST-ADMINISTRATION	2.117	ng/mL

Listing 16.2.5.1
Serum Concentrations

Age/Sex/ Subject Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units	
08	31/F/Ca	Subject-specific, UB Cigarette	COTININE	01NOV2011/09:23:12	PRE-ADMINISTRATION	166	ng/mL
				01NOV2011/09:24:50	0 MINUTES POST-ADMINISTRATION	169	ng/mL
				01NOV2011/09:27:45	3 MINUTES POST-ADMINISTRATION	167	ng/mL
				01NOV2011/09:29:45	5 MINUTES POST-ADMINISTRATION	166	ng/mL
				01NOV2011/09:32:11	7.5 MINUTES POST-ADMINISTRATION	165	ng/mL
				01NOV2011/09:34:41	10 MINUTES POST-ADMINISTRATION	162	ng/mL
				01NOV2011/09:39:28	15 MINUTES POST-ADMINISTRATION	165	ng/mL
				01NOV2011/09:44:32	20 MINUTES POST-ADMINISTRATION	167	ng/mL
				01NOV2011/09:54:43	30 MINUTES POST-ADMINISTRATION	167	ng/mL
				01NOV2011/10:09:25	45 MINUTES POST-ADMINISTRATION	167	ng/mL
				01NOV2011/10:24:35	60 MINUTES POST-ADMINISTRATION	167	ng/mL
				01NOV2011/10:39:31	75 MINUTES POST-ADMINISTRATION	167	ng/mL
				01NOV2011/10:54:38	90 MINUTES POST-ADMINISTRATION	171	ng/mL
				01NOV2011/11:23:37	120 MINUTES POST-ADMINISTRATION	171	ng/mL
				01NOV2011/11:53:46	150 MINUTES POST-ADMINISTRATION	161	ng/mL
				01NOV2011/12:23:39	180 MINUTES POST-ADMINISTRATION	161	ng/mL

Listing 16.2.5.1
Serum Concentrations

Subject	Age/Sex/ Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units
08	31/F/Ca	Subject-specific, UB Cigarette	NICOTINE	01NOV2011/09:23:12	PRE-ADMINISTRATION	1.05	ng/mL
				01NOV2011/09:24:50	0 MINUTES POST-ADMINISTRATION	1.16	ng/mL
				01NOV2011/09:27:45	3 MINUTES POST-ADMINISTRATION	4.98	ng/mL
				01NOV2011/09:29:45	5 MINUTES POST-ADMINISTRATION	7.99	ng/mL
				01NOV2011/09:32:11	7.5 MINUTES POST-ADMINISTRATION	9.39	ng/mL
				01NOV2011/09:34:41	10 MINUTES POST-ADMINISTRATION	9.76	ng/mL
				01NOV2011/09:39:28	15 MINUTES POST-ADMINISTRATION	9.94	ng/mL
				01NOV2011/09:44:32	20 MINUTES POST-ADMINISTRATION	9.8	ng/mL
				01NOV2011/09:54:43	30 MINUTES POST-ADMINISTRATION	7.86	ng/mL
				01NOV2011/10:09:25	45 MINUTES POST-ADMINISTRATION	6.91	ng/mL
				01NOV2011/10:24:35	60 MINUTES POST-ADMINISTRATION	6.59	ng/mL
				01NOV2011/10:39:31	75 MINUTES POST-ADMINISTRATION	6.08	ng/mL
				01NOV2011/10:54:38	90 MINUTES POST-ADMINISTRATION	5.7	ng/mL
				01NOV2011/11:23:37	120 MINUTES POST-ADMINISTRATION	5.2	ng/mL
				01NOV2011/11:53:46	150 MINUTES POST-ADMINISTRATION	4.54	ng/mL
				01NOV2011/12:23:39	180 MINUTES POST-ADMINISTRATION	4.45	ng/mL
		NICOTINE ADJ	01NOV2011/09:24:50	0 MINUTES POST-ADMINISTRATION	0.000	ng/mL	
			01NOV2011/09:27:45	3 MINUTES POST-ADMINISTRATION	3.840	ng/mL	
			01NOV2011/09:29:45	5 MINUTES POST-ADMINISTRATION	6.863	ng/mL	
			01NOV2011/09:32:11	7.5 MINUTES POST-ADMINISTRATION	8.279	ng/mL	
			01NOV2011/09:34:41	10 MINUTES POST-ADMINISTRATION	8.665	ng/mL	
			01NOV2011/09:39:28	15 MINUTES POST-ADMINISTRATION	8.876	ng/mL	
			01NOV2011/09:44:32	20 MINUTES POST-ADMINISTRATION	8.767	ng/mL	
			01NOV2011/09:54:43	30 MINUTES POST-ADMINISTRATION	6.885	ng/mL	
			01NOV2011/10:09:25	45 MINUTES POST-ADMINISTRATION	6.016	ng/mL	
			01NOV2011/10:24:35	60 MINUTES POST-ADMINISTRATION	5.770	ng/mL	
			01NOV2011/10:39:31	75 MINUTES POST-ADMINISTRATION	5.328	ng/mL	
			01NOV2011/10:54:38	90 MINUTES POST-ADMINISTRATION	5.010	ng/mL	
			01NOV2011/11:23:37	120 MINUTES POST-ADMINISTRATION	4.620	ng/mL	
			01NOV2011/11:53:46	150 MINUTES POST-ADMINISTRATION	4.052	ng/mL	
			01NOV2011/12:23:39	180 MINUTES POST-ADMINISTRATION	4.040	ng/mL	

Listing 16.2.5.1
Serum Concentrations

Subject	Age/Sex/ Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units
08	31/F/Ca	Camel SNUS	COTININE	08NOV2011/08:55:04	PRE-ADMINISTRATION	120	ng/mL
				08NOV2011/08:55:57	0 MINUTES POST-ADMINISTRATION	126	ng/mL
				08NOV2011/08:58:42	3 MINUTES POST-ADMINISTRATION	123	ng/mL
				08NOV2011/09:00:54	5 MINUTES POST-ADMINISTRATION	134	ng/mL
				08NOV2011/09:03:14	7.5 MINUTES POST-ADMINISTRATION	120	ng/mL
				08NOV2011/09:05:42	10 MINUTES POST-ADMINISTRATION	119	ng/mL
				08NOV2011/09:10:43	15 MINUTES POST-ADMINISTRATION	121	ng/mL
				08NOV2011/09:15:49	20 MINUTES POST-ADMINISTRATION	120	ng/mL
				08NOV2011/09:25:44	30 MINUTES POST-ADMINISTRATION	127	ng/mL
				08NOV2011/09:40:42	45 MINUTES POST-ADMINISTRATION	124	ng/mL
				08NOV2011/09:55:41	60 MINUTES POST-ADMINISTRATION	119	ng/mL
				08NOV2011/10:10:46	75 MINUTES POST-ADMINISTRATION	119	ng/mL
				08NOV2011/10:25:46	90 MINUTES POST-ADMINISTRATION	118	ng/mL
				08NOV2011/10:54:51	120 MINUTES POST-ADMINISTRATION	115	ng/mL
				08NOV2011/11:24:53	150 MINUTES POST-ADMINISTRATION	116	ng/mL
				08NOV2011/11:54:52	180 MINUTES POST-ADMINISTRATION	118	ng/mL
			NICOTINE	08NOV2011/08:55:04	PRE-ADMINISTRATION	BLQ<(0.500)	ng/mL
				08NOV2011/08:55:57	0 MINUTES POST-ADMINISTRATION	0.506	ng/mL
				08NOV2011/08:58:42	3 MINUTES POST-ADMINISTRATION	0.593	ng/mL
				08NOV2011/09:00:54	5 MINUTES POST-ADMINISTRATION	0.894	ng/mL
				08NOV2011/09:03:14	7.5 MINUTES POST-ADMINISTRATION	1.22	ng/mL
				08NOV2011/09:05:42	10 MINUTES POST-ADMINISTRATION	1.45	ng/mL
				08NOV2011/09:10:43	15 MINUTES POST-ADMINISTRATION	1.57	ng/mL
				08NOV2011/09:15:49	20 MINUTES POST-ADMINISTRATION	1.73	ng/mL
				08NOV2011/09:25:44	30 MINUTES POST-ADMINISTRATION	1.86	ng/mL
				08NOV2011/09:40:42	45 MINUTES POST-ADMINISTRATION	1.79	ng/mL
				08NOV2011/09:55:41	60 MINUTES POST-ADMINISTRATION	1.55	ng/mL
				08NOV2011/10:10:46	75 MINUTES POST-ADMINISTRATION	1.53	ng/mL
				08NOV2011/10:25:46	90 MINUTES POST-ADMINISTRATION	1.46	ng/mL
				08NOV2011/10:54:51	120 MINUTES POST-ADMINISTRATION	1.23	ng/mL
				08NOV2011/11:24:53	150 MINUTES POST-ADMINISTRATION	1.25	ng/mL
				08NOV2011/11:54:52	180 MINUTES POST-ADMINISTRATION	1.15	ng/mL

Listing 16.2.5.1
Serum Concentrations

Subject	Age/Sex/ Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units
08	31/F/Ca	Camel SNUS	NICOTINE ADJ	08NOV2011/08:55:57	0 MINUTES POST-ADMINISTRATION	0.000	ng/mL
				08NOV2011/08:58:42	3 MINUTES POST-ADMINISTRATION	0.096	ng/mL
				08NOV2011/09:00:54	5 MINUTES POST-ADMINISTRATION	0.402	ng/mL
				08NOV2011/09:03:14	7.5 MINUTES POST-ADMINISTRATION	0.735	ng/mL
				08NOV2011/09:05:42	10 MINUTES POST-ADMINISTRATION	0.972	ng/mL
				08NOV2011/09:10:43	15 MINUTES POST-ADMINISTRATION	1.106	ng/mL
				08NOV2011/09:15:49	20 MINUTES POST-ADMINISTRATION	1.279	ng/mL
				08NOV2011/09:25:44	30 MINUTES POST-ADMINISTRATION	1.435	ng/mL
				08NOV2011/09:40:42	45 MINUTES POST-ADMINISTRATION	1.400	ng/mL
				08NOV2011/09:55:41	60 MINUTES POST-ADMINISTRATION	1.192	ng/mL
				08NOV2011/10:10:46	75 MINUTES POST-ADMINISTRATION	1.202	ng/mL
				08NOV2011/10:25:46	90 MINUTES POST-ADMINISTRATION	1.159	ng/mL
				08NOV2011/10:54:51	120 MINUTES POST-ADMINISTRATION	0.977	ng/mL
				08NOV2011/11:24:53	150 MINUTES POST-ADMINISTRATION	1.037	ng/mL
				08NOV2011/11:54:52	180 MINUTES POST-ADMINISTRATION	0.971	ng/mL

(b) (4)

Listing 16.2.5.1
Serum Concentrations

(b) (4)



Listing 16.2.5.1
Serum Concentrations

(b) (4)



Listing 16.2.5.1
Serum Concentrations

(b) (4)



Listing 16.2.5.1
Serum Concentrations

(b) (4)



Listing 16.2.5.1
Serum Concentrations

	Age/Sex/ Subject Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units
09	47/F/Ca	Subject-specific, UB Cigarette	COTININE	02NOV2011/09:13:30	PRE-ADMINISTRATION	216	ng/mL
				02NOV2011/09:14:35	0 MINUTES POST-ADMINISTRATION	205	ng/mL
				02NOV2011/09:17:34	3 MINUTES POST-ADMINISTRATION	204	ng/mL
				02NOV2011/09:19:34	5 MINUTES POST-ADMINISTRATION	206	ng/mL
				02NOV2011/09:21:59	7.5 MINUTES POST-ADMINISTRATION	200	ng/mL
				02NOV2011/09:24:34	10 MINUTES POST-ADMINISTRATION	200	ng/mL
				02NOV2011/09:29:35	15 MINUTES POST-ADMINISTRATION	209	ng/mL
				02NOV2011/09:34:37	20 MINUTES POST-ADMINISTRATION	199	ng/mL
				02NOV2011/09:44:34	30 MINUTES POST-ADMINISTRATION	204	ng/mL
				02NOV2011/09:59:34	45 MINUTES POST-ADMINISTRATION	206	ng/mL
				02NOV2011/10:14:33	60 MINUTES POST-ADMINISTRATION	202	ng/mL
				02NOV2011/10:29:34	75 MINUTES POST-ADMINISTRATION	194	ng/mL
				02NOV2011/10:44:34	90 MINUTES POST-ADMINISTRATION	210	ng/mL
				02NOV2011/11:14:37	120 MINUTES POST-ADMINISTRATION	188	ng/mL
				02NOV2011/11:44:36	150 MINUTES POST-ADMINISTRATION	181	ng/mL
				02NOV2011/12:14:36	180 MINUTES POST-ADMINISTRATION	190	ng/mL
			NICOTINE	02NOV2011/09:13:30	PRE-ADMINISTRATION	0.876	ng/mL
				02NOV2011/09:14:35	0 MINUTES POST-ADMINISTRATION	1.15	ng/mL
				02NOV2011/09:17:34	3 MINUTES POST-ADMINISTRATION	7.68	ng/mL
				02NOV2011/09:19:34	5 MINUTES POST-ADMINISTRATION	10	ng/mL
				02NOV2011/09:21:59	7.5 MINUTES POST-ADMINISTRATION	12.1	ng/mL
				02NOV2011/09:24:34	10 MINUTES POST-ADMINISTRATION	9.78	ng/mL
				02NOV2011/09:29:35	15 MINUTES POST-ADMINISTRATION	9.1	ng/mL
				02NOV2011/09:34:37	20 MINUTES POST-ADMINISTRATION	8.22	ng/mL
				02NOV2011/09:44:34	30 MINUTES POST-ADMINISTRATION	7.92	ng/mL
				02NOV2011/09:59:34	45 MINUTES POST-ADMINISTRATION	6.63	ng/mL
				02NOV2011/10:14:33	60 MINUTES POST-ADMINISTRATION	5.69	ng/mL
				02NOV2011/10:29:34	75 MINUTES POST-ADMINISTRATION	5.32	ng/mL
				02NOV2011/10:44:34	90 MINUTES POST-ADMINISTRATION	4.81	ng/mL
				02NOV2011/11:14:37	120 MINUTES POST-ADMINISTRATION	3.22	ng/mL
				02NOV2011/11:44:36	150 MINUTES POST-ADMINISTRATION	3.15	ng/mL
				02NOV2011/12:14:36	180 MINUTES POST-ADMINISTRATION	2.46	ng/mL

Listing 16.2.5.1
Serum Concentrations

Subject	Age/Sex/ Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units
09	47/F/Ca	Subject-specific, UB Cigarette	NICOTINE ADJ	02NOV2011/09:14:35	0 MINUTES POST-ADMINISTRATION	0.000	ng/mL
				02NOV2011/09:17:34	3 MINUTES POST-ADMINISTRATION	6.550	ng/mL
				02NOV2011/09:19:34	5 MINUTES POST-ADMINISTRATION	8.883	ng/mL
				02NOV2011/09:21:59	7.5 MINUTES POST-ADMINISTRATION	10.999	ng/mL
				02NOV2011/09:24:34	10 MINUTES POST-ADMINISTRATION	8.695	ng/mL
				02NOV2011/09:29:35	15 MINUTES POST-ADMINISTRATION	8.045	ng/mL
				02NOV2011/09:34:37	20 MINUTES POST-ADMINISTRATION	7.195	ng/mL
				02NOV2011/09:44:34	30 MINUTES POST-ADMINISTRATION	6.953	ng/mL
				02NOV2011/09:59:34	45 MINUTES POST-ADMINISTRATION	5.743	ng/mL
				02NOV2011/10:14:33	60 MINUTES POST-ADMINISTRATION	4.877	ng/mL
				02NOV2011/10:29:34	75 MINUTES POST-ADMINISTRATION	4.574	ng/mL
				02NOV2011/10:44:34	90 MINUTES POST-ADMINISTRATION	4.126	ng/mL
				02NOV2011/11:14:37	120 MINUTES POST-ADMINISTRATION	2.645	ng/mL
				02NOV2011/11:44:36	150 MINUTES POST-ADMINISTRATION	2.666	ng/mL
				02NOV2011/12:14:36	180 MINUTES POST-ADMINISTRATION	2.053	ng/mL

(b) (4)



Listing 16.2.5.1
Serum Concentrations

(b) (4)



Listing 16.2.5.1
Serum Concentrations

(b) (4)



Listing 16.2.5.1
Serum Concentrations

(b) (4)



Listing 16.2.5.1
Serum Concentrations

Age/Sex/ Subject Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units
09	47/F/Ca Camel SNUS	NICOTINE	30NOV2011/08:53:10	PRE-ADMINISTRATION	1.11	ng/mL
			30NOV2011/08:53:43	0 MINUTES POST-ADMINISTRATION	0.733	ng/mL
			30NOV2011/08:56:36	3 MINUTES POST-ADMINISTRATION	2.77	ng/mL
			30NOV2011/08:58:36	5 MINUTES POST-ADMINISTRATION	1.98	ng/mL
			30NOV2011/09:01:25	7.5 MINUTES POST-ADMINISTRATION	2.58	ng/mL
			30NOV2011/09:03:35	10 MINUTES POST-ADMINISTRATION	2.66	ng/mL
			30NOV2011/09:08:35	15 MINUTES POST-ADMINISTRATION	4.12	ng/mL
			30NOV2011/09:13:36	20 MINUTES POST-ADMINISTRATION	3.42	ng/mL
			30NOV2011/09:23:37	30 MINUTES POST-ADMINISTRATION	2.95	ng/mL
			30NOV2011/09:38:34	45 MINUTES POST-ADMINISTRATION	2.62	ng/mL
			30NOV2011/09:53:40	60 MINUTES POST-ADMINISTRATION	2.23	ng/mL
			30NOV2011/10:08:35	75 MINUTES POST-ADMINISTRATION	2.03	ng/mL
			30NOV2011/10:23:37	90 MINUTES POST-ADMINISTRATION	1.94	ng/mL
			30NOV2011/10:53:32	120 MINUTES POST-ADMINISTRATION	1.91	ng/mL
			30NOV2011/11:23:34	150 MINUTES POST-ADMINISTRATION	1.36	ng/mL
			30NOV2011/11:53:39	180 MINUTES POST-ADMINISTRATION	1.29	ng/mL
		NICOTINE ADJ	30NOV2011/08:53:43	0 MINUTES POST-ADMINISTRATION	0.000	ng/mL
			30NOV2011/08:56:36	3 MINUTES POST-ADMINISTRATION	2.050	ng/mL
			30NOV2011/08:58:36	5 MINUTES POST-ADMINISTRATION	1.268	ng/mL
			30NOV2011/09:01:25	7.5 MINUTES POST-ADMINISTRATION	1.878	ng/mL
			30NOV2011/09:03:35	10 MINUTES POST-ADMINISTRATION	1.968	ng/mL
			30NOV2011/09:08:35	15 MINUTES POST-ADMINISTRATION	3.448	ng/mL
			30NOV2011/09:13:36	20 MINUTES POST-ADMINISTRATION	2.767	ng/mL
			30NOV2011/09:23:37	30 MINUTES POST-ADMINISTRATION	2.334	ng/mL
			30NOV2011/09:38:34	45 MINUTES POST-ADMINISTRATION	2.055	ng/mL
			30NOV2011/09:53:40	60 MINUTES POST-ADMINISTRATION	1.712	ng/mL
			30NOV2011/10:08:35	75 MINUTES POST-ADMINISTRATION	1.555	ng/mL
			30NOV2011/10:23:37	90 MINUTES POST-ADMINISTRATION	1.504	ng/mL
			30NOV2011/10:53:32	120 MINUTES POST-ADMINISTRATION	1.544	ng/mL
			30NOV2011/11:23:34	150 MINUTES POST-ADMINISTRATION	1.052	ng/mL
			30NOV2011/11:53:39	180 MINUTES POST-ADMINISTRATION	1.031	ng/mL

Listing 16.2.5.1
Serum Concentrations

(b) (4)



Listing 16.2.5.1
Serum Concentrations

(b) (4)



Listing 16.2.5.1
Serum Concentrations

Age/Sex/ Subject Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units	
10	41/F/Ca	Subject-specific, UB Cigarette	COTININE	02NOV2011/09:09:35	PRE-ADMINISTRATION	215	ng/mL
				02NOV2011/09:12:29	0 MINUTES POST-ADMINISTRATION	228	ng/mL
				02NOV2011/09:15:32	3 MINUTES POST-ADMINISTRATION	214	ng/mL
				02NOV2011/09:17:32	5 MINUTES POST-ADMINISTRATION	214	ng/mL
				02NOV2011/09:20:01	7.5 MINUTES POST-ADMINISTRATION	256	ng/mL
				02NOV2011/09:22:30	10 MINUTES POST-ADMINISTRATION	218	ng/mL
				02NOV2011/09:27:30	15 MINUTES POST-ADMINISTRATION	216	ng/mL
				02NOV2011/09:32:32	20 MINUTES POST-ADMINISTRATION	215	ng/mL
				02NOV2011/09:42:30	30 MINUTES POST-ADMINISTRATION	214	ng/mL
				02NOV2011/09:57:31	45 MINUTES POST-ADMINISTRATION	219	ng/mL
				02NOV2011/10:12:29	60 MINUTES POST-ADMINISTRATION	214	ng/mL
				02NOV2011/10:27:29	75 MINUTES POST-ADMINISTRATION	212	ng/mL
				02NOV2011/10:42:29	90 MINUTES POST-ADMINISTRATION	223	ng/mL
				02NOV2011/11:12:31	120 MINUTES POST-ADMINISTRATION	211	ng/mL
				02NOV2011/11:42:35	150 MINUTES POST-ADMINISTRATION	207	ng/mL
				02NOV2011/12:12:35	180 MINUTES POST-ADMINISTRATION	201	ng/mL

Listing 16.2.5.1
Serum Concentrations

Age/Sex/ Subject Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units	
10	41/F/Ca	Subject-specific, UB Cigarette	NICOTINE	02NOV2011/09:09:35	PRE-ADMINISTRATION	0.981	ng/mL
				02NOV2011/09:12:29	0 MINUTES POST-ADMINISTRATION	0.837	ng/mL
				02NOV2011/09:15:32	3 MINUTES POST-ADMINISTRATION	2.65	ng/mL
				02NOV2011/09:17:32	5 MINUTES POST-ADMINISTRATION	3.44	ng/mL
				02NOV2011/09:20:01	7.5 MINUTES POST-ADMINISTRATION	7.18	ng/mL
				02NOV2011/09:22:30	10 MINUTES POST-ADMINISTRATION	7.16	ng/mL
				02NOV2011/09:27:30	15 MINUTES POST-ADMINISTRATION	7.08	ng/mL
				02NOV2011/09:32:32	20 MINUTES POST-ADMINISTRATION	7.54	ng/mL
				02NOV2011/09:42:30	30 MINUTES POST-ADMINISTRATION	7.26	ng/mL
				02NOV2011/09:57:31	45 MINUTES POST-ADMINISTRATION	6.08	ng/mL
				02NOV2011/10:12:29	60 MINUTES POST-ADMINISTRATION	4.87	ng/mL
				02NOV2011/10:27:29	75 MINUTES POST-ADMINISTRATION	3.92	ng/mL
				02NOV2011/10:42:29	90 MINUTES POST-ADMINISTRATION	3.76	ng/mL
				02NOV2011/11:12:31	120 MINUTES POST-ADMINISTRATION	3.46	ng/mL
				02NOV2011/11:42:35	150 MINUTES POST-ADMINISTRATION	2.69	ng/mL
				02NOV2011/12:12:35	180 MINUTES POST-ADMINISTRATION	2.29	ng/mL
		NICOTINE ADJ		02NOV2011/09:12:29	0 MINUTES POST-ADMINISTRATION	0.000	ng/mL
				02NOV2011/09:15:32	3 MINUTES POST-ADMINISTRATION	1.827	ng/mL
				02NOV2011/09:17:32	5 MINUTES POST-ADMINISTRATION	2.627	ng/mL
				02NOV2011/09:20:01	7.5 MINUTES POST-ADMINISTRATION	6.378	ng/mL
				02NOV2011/09:22:30	10 MINUTES POST-ADMINISTRATION	6.370	ng/mL
				02NOV2011/09:27:30	15 MINUTES POST-ADMINISTRATION	6.312	ng/mL
				02NOV2011/09:32:32	20 MINUTES POST-ADMINISTRATION	6.794	ng/mL
				02NOV2011/09:42:30	30 MINUTES POST-ADMINISTRATION	6.556	ng/mL
				02NOV2011/09:57:31	45 MINUTES POST-ADMINISTRATION	5.435	ng/mL
				02NOV2011/10:12:29	60 MINUTES POST-ADMINISTRATION	4.278	ng/mL
				02NOV2011/10:27:29	75 MINUTES POST-ADMINISTRATION	3.377	ng/mL
				02NOV2011/10:42:29	90 MINUTES POST-ADMINISTRATION	3.262	ng/mL
				02NOV2011/11:12:31	120 MINUTES POST-ADMINISTRATION	3.042	ng/mL
				02NOV2011/11:42:35	150 MINUTES POST-ADMINISTRATION	2.338	ng/mL
				02NOV2011/12:12:35	180 MINUTES POST-ADMINISTRATION	1.994	ng/mL

Listing 16.2.5.1
Serum Concentrations

Subject	Age/Sex/ Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units
10	41/F/Ca	Camel SNUS	COTININE	09NOV2011/09:07:18	PRE-ADMINISTRATION	253	ng/mL
				09NOV2011/09:08:09	0 MINUTES POST-ADMINISTRATION	248	ng/mL
				09NOV2011/09:11:14	3 MINUTES POST-ADMINISTRATION	251	ng/mL
				09NOV2011/09:13:09	5 MINUTES POST-ADMINISTRATION	263	ng/mL
				09NOV2011/09:15:39	7.5 MINUTES POST-ADMINISTRATION	248	ng/mL
				09NOV2011/09:18:14	10 MINUTES POST-ADMINISTRATION	244	ng/mL
				09NOV2011/09:23:09	15 MINUTES POST-ADMINISTRATION	247	ng/mL
				09NOV2011/09:28:09	20 MINUTES POST-ADMINISTRATION	247	ng/mL
				09NOV2011/09:38:09	30 MINUTES POST-ADMINISTRATION	245	ng/mL
				09NOV2011/09:53:09	45 MINUTES POST-ADMINISTRATION	258	ng/mL
				09NOV2011/10:08:08	60 MINUTES POST-ADMINISTRATION	257	ng/mL
				09NOV2011/10:23:09	75 MINUTES POST-ADMINISTRATION	257	ng/mL
				09NOV2011/10:38:08	90 MINUTES POST-ADMINISTRATION	268	ng/mL
				09NOV2011/11:08:07	120 MINUTES POST-ADMINISTRATION	266	ng/mL
				09NOV2011/11:38:06	150 MINUTES POST-ADMINISTRATION	262	ng/mL
				09NOV2011/12:08:09	180 MINUTES POST-ADMINISTRATION	256	ng/mL
			NICOTINE	09NOV2011/09:07:18	PRE-ADMINISTRATION	1.92	ng/mL
				09NOV2011/09:08:09	0 MINUTES POST-ADMINISTRATION	2.19	ng/mL
				09NOV2011/09:11:14	3 MINUTES POST-ADMINISTRATION	1.99	ng/mL
				09NOV2011/09:13:09	5 MINUTES POST-ADMINISTRATION	2.28	ng/mL
				09NOV2011/09:15:39	7.5 MINUTES POST-ADMINISTRATION	2.69	ng/mL
				09NOV2011/09:18:14	10 MINUTES POST-ADMINISTRATION	3.04	ng/mL
				09NOV2011/09:23:09	15 MINUTES POST-ADMINISTRATION	4.72	ng/mL
				09NOV2011/09:28:09	20 MINUTES POST-ADMINISTRATION	5.34	ng/mL
				09NOV2011/09:38:09	30 MINUTES POST-ADMINISTRATION	5.35	ng/mL
				09NOV2011/09:53:09	45 MINUTES POST-ADMINISTRATION	6.77	ng/mL
				09NOV2011/10:08:08	60 MINUTES POST-ADMINISTRATION	7.43	ng/mL
				09NOV2011/10:23:09	75 MINUTES POST-ADMINISTRATION	6.49	ng/mL
				09NOV2011/10:38:08	90 MINUTES POST-ADMINISTRATION	5.87	ng/mL
				09NOV2011/11:08:07	120 MINUTES POST-ADMINISTRATION	4.49	ng/mL
				09NOV2011/11:38:06	150 MINUTES POST-ADMINISTRATION	3.42	ng/mL
				09NOV2011/12:08:09	180 MINUTES POST-ADMINISTRATION	3.67	ng/mL

Listing 16.2.5.1
Serum Concentrations

Subject	Age/Sex/ Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units
10	41/F/Ca	Camel SNUS	NICOTINE ADJ	09NOV2011/09:08:09	0 MINUTES POST-ADMINISTRATION	0.000	ng/mL
				09NOV2011/09:11:14	3 MINUTES POST-ADMINISTRATION	0.000	ng/mL
				09NOV2011/09:13:09	5 MINUTES POST-ADMINISTRATION	0.152	ng/mL
				09NOV2011/09:15:39	7.5 MINUTES POST-ADMINISTRATION	0.593	ng/mL
				09NOV2011/09:18:14	10 MINUTES POST-ADMINISTRATION	0.973	ng/mL
				09NOV2011/09:23:09	15 MINUTES POST-ADMINISTRATION	2.712	ng/mL
				09NOV2011/09:28:09	20 MINUTES POST-ADMINISTRATION	3.389	ng/mL
				09NOV2011/09:38:09	30 MINUTES POST-ADMINISTRATION	3.508	ng/mL
				09NOV2011/09:53:09	45 MINUTES POST-ADMINISTRATION	5.081	ng/mL
				09NOV2011/10:08:08	60 MINUTES POST-ADMINISTRATION	5.881	ng/mL
				09NOV2011/10:23:09	75 MINUTES POST-ADMINISTRATION	5.070	ng/mL
				09NOV2011/10:38:08	90 MINUTES POST-ADMINISTRATION	4.568	ng/mL
				09NOV2011/11:08:07	120 MINUTES POST-ADMINISTRATION	3.395	ng/mL
				09NOV2011/11:38:06	150 MINUTES POST-ADMINISTRATION	2.499	ng/mL
				09NOV2011/12:08:09	180 MINUTES POST-ADMINISTRATION	2.896	ng/mL

(b) (4)

Listing 16.2.5.1
Serum Concentrations

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Listing 16.2.5.1
Serum Concentrations

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Listing 16.2.5.1
Serum Concentrations

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Listing 16.2.5.1
Serum Concentrations

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Listing 16.2.5.1
Serum Concentrations

Subject	Age/Sex/ Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units
11	32/F/Af	Subject-specific, UB Cigarette	COTININE	02NOV2011/09:13:55	PRE-ADMINISTRATION	253	ng/mL
				02NOV2011/09:14:24	0 MINUTES POST-ADMINISTRATION	249	ng/mL
				02NOV2011/09:17:22	3 MINUTES POST-ADMINISTRATION	254	ng/mL
				02NOV2011/09:19:23	5 MINUTES POST-ADMINISTRATION	241	ng/mL
				02NOV2011/09:21:52	7.5 MINUTES POST-ADMINISTRATION	254	ng/mL
				02NOV2011/09:24:23	10 MINUTES POST-ADMINISTRATION	251	ng/mL
				02NOV2011/09:29:23	15 MINUTES POST-ADMINISTRATION	252	ng/mL
				02NOV2011/09:34:23	20 MINUTES POST-ADMINISTRATION	259	ng/mL
				02NOV2011/09:44:22	30 MINUTES POST-ADMINISTRATION	261	ng/mL
				02NOV2011/09:59:22	45 MINUTES POST-ADMINISTRATION	253	ng/mL
				02NOV2011/10:14:22	60 MINUTES POST-ADMINISTRATION	251	ng/mL
				02NOV2011/10:29:24	75 MINUTES POST-ADMINISTRATION	255	ng/mL
				02NOV2011/10:50:11	90 MINUTES POST-ADMINISTRATION	245	ng/mL
				02NOV2011/11:14:24	120 MINUTES POST-ADMINISTRATION	246	ng/mL
				02NOV2011/11:44:23	150 MINUTES POST-ADMINISTRATION	240	ng/mL
				02NOV2011/12:14:26	180 MINUTES POST-ADMINISTRATION	232	ng/mL
			NICOTINE	02NOV2011/09:13:55	PRE-ADMINISTRATION	0.958	ng/mL
				02NOV2011/09:14:24	0 MINUTES POST-ADMINISTRATION	0.992	ng/mL
				02NOV2011/09:17:22	3 MINUTES POST-ADMINISTRATION	19	ng/mL
				02NOV2011/09:19:23	5 MINUTES POST-ADMINISTRATION	30.9	ng/mL
				02NOV2011/09:21:52	7.5 MINUTES POST-ADMINISTRATION	19.6	ng/mL
				02NOV2011/09:24:23	10 MINUTES POST-ADMINISTRATION	14.6	ng/mL
				02NOV2011/09:29:23	15 MINUTES POST-ADMINISTRATION	11.6	ng/mL
				02NOV2011/09:34:23	20 MINUTES POST-ADMINISTRATION	9.01	ng/mL
				02NOV2011/09:44:22	30 MINUTES POST-ADMINISTRATION	7.52	ng/mL
				02NOV2011/09:59:22	45 MINUTES POST-ADMINISTRATION	5.28	ng/mL
				02NOV2011/10:14:22	60 MINUTES POST-ADMINISTRATION	4.31	ng/mL
				02NOV2011/10:29:24	75 MINUTES POST-ADMINISTRATION	4.79	ng/mL
				02NOV2011/10:50:11	90 MINUTES POST-ADMINISTRATION	3.86	ng/mL
				02NOV2011/11:14:24	120 MINUTES POST-ADMINISTRATION	3.4	ng/mL
				02NOV2011/11:44:23	150 MINUTES POST-ADMINISTRATION	2.48	ng/mL
				02NOV2011/12:14:26	180 MINUTES POST-ADMINISTRATION	2.45	ng/mL

Listing 16.2.5.1
Serum Concentrations

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Listing 16.2.5.1
Serum Concentrations

(b) (4)



Listing 16.2.5.1
Serum Concentrations

Subject	Age/Sex/ Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units
11	32/F/Af	Camel SNUS	COTININE	30NOV2011/08:51:20	PRE-ADMINISTRATION	184	ng/mL
				30NOV2011/08:52:01	0 MINUTES POST-ADMINISTRATION	182	ng/mL
				30NOV2011/08:55:01	3 MINUTES POST-ADMINISTRATION	183	ng/mL
				30NOV2011/08:57:01	5 MINUTES POST-ADMINISTRATION	185	ng/mL
				30NOV2011/08:59:29	7.5 MINUTES POST-ADMINISTRATION	182	ng/mL
				30NOV2011/09:02:02	10 MINUTES POST-ADMINISTRATION	182	ng/mL
				30NOV2011/09:07:01	15 MINUTES POST-ADMINISTRATION	184	ng/mL
				30NOV2011/09:12:01	20 MINUTES POST-ADMINISTRATION	183	ng/mL
				30NOV2011/09:22:01	30 MINUTES POST-ADMINISTRATION	185	ng/mL
				30NOV2011/09:37:00	45 MINUTES POST-ADMINISTRATION	186	ng/mL
				30NOV2011/09:52:01	60 MINUTES POST-ADMINISTRATION	188	ng/mL
				30NOV2011/10:07:01	75 MINUTES POST-ADMINISTRATION	189	ng/mL
				30NOV2011/10:22:01	90 MINUTES POST-ADMINISTRATION	184	ng/mL
				30NOV2011/10:52:01	120 MINUTES POST-ADMINISTRATION	183	ng/mL
				30NOV2011/11:22:01	150 MINUTES POST-ADMINISTRATION	182	ng/mL
				30NOV2011/11:52:01	180 MINUTES POST-ADMINISTRATION	174	ng/mL
			NICOTINE	30NOV2011/08:51:20	PRE-ADMINISTRATION	0.801	ng/mL
				30NOV2011/08:52:01	0 MINUTES POST-ADMINISTRATION	0.868	ng/mL
				30NOV2011/08:55:01	3 MINUTES POST-ADMINISTRATION	1.2	ng/mL
				30NOV2011/08:57:01	5 MINUTES POST-ADMINISTRATION	1.65	ng/mL
				30NOV2011/08:59:29	7.5 MINUTES POST-ADMINISTRATION	1.59	ng/mL
				30NOV2011/09:02:02	10 MINUTES POST-ADMINISTRATION	1.67	ng/mL
				30NOV2011/09:07:01	15 MINUTES POST-ADMINISTRATION	1.96	ng/mL
				30NOV2011/09:12:01	20 MINUTES POST-ADMINISTRATION	2.14	ng/mL
				30NOV2011/09:22:01	30 MINUTES POST-ADMINISTRATION	1.87	ng/mL
				30NOV2011/09:37:00	45 MINUTES POST-ADMINISTRATION	1.73	ng/mL
				30NOV2011/09:52:01	60 MINUTES POST-ADMINISTRATION	1.49	ng/mL
				30NOV2011/10:07:01	75 MINUTES POST-ADMINISTRATION	1.47	ng/mL
				30NOV2011/10:22:01	90 MINUTES POST-ADMINISTRATION	1.46	ng/mL
				30NOV2011/10:52:01	120 MINUTES POST-ADMINISTRATION	1.22	ng/mL
				30NOV2011/11:22:01	150 MINUTES POST-ADMINISTRATION	1.16	ng/mL
				30NOV2011/11:52:01	180 MINUTES POST-ADMINISTRATION	1.01	ng/mL

Listing 16.2.5.1
Serum Concentrations

Subject	Age/Sex/ Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units
11	32/F/Af	Camel SNUS	NICOTINE ADJ	30NOV2011/08:52:01	0 MINUTES POST-ADMINISTRATION	0.000	ng/mL
				30NOV2011/08:55:01	3 MINUTES POST-ADMINISTRATION	0.347	ng/mL
				30NOV2011/08:57:01	5 MINUTES POST-ADMINISTRATION	0.807	ng/mL
				30NOV2011/08:59:29	7.5 MINUTES POST-ADMINISTRATION	0.759	ng/mL
				30NOV2011/09:02:02	10 MINUTES POST-ADMINISTRATION	0.851	ng/mL
				30NOV2011/09:07:01	15 MINUTES POST-ADMINISTRATION	1.164	ng/mL
				30NOV2011/09:12:01	20 MINUTES POST-ADMINISTRATION	1.367	ng/mL
				30NOV2011/09:22:01	30 MINUTES POST-ADMINISTRATION	1.140	ng/mL
				30NOV2011/09:37:00	45 MINUTES POST-ADMINISTRATION	1.061	ng/mL
				30NOV2011/09:52:01	60 MINUTES POST-ADMINISTRATION	0.876	ng/mL
				30NOV2011/10:07:01	75 MINUTES POST-ADMINISTRATION	0.907	ng/mL
				30NOV2011/10:22:01	90 MINUTES POST-ADMINISTRATION	0.944	ng/mL
				30NOV2011/10:52:01	120 MINUTES POST-ADMINISTRATION	0.786	ng/mL
				30NOV2011/11:22:01	150 MINUTES POST-ADMINISTRATION	0.795	ng/mL
				30NOV2011/11:52:01	180 MINUTES POST-ADMINISTRATION	0.703	ng/mL

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Listing 16.2.5.1
Serum Concentrations

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Listing 16.2.5.1
Serum Concentrations

(b) (4)



Listing 16.2.5.1
Serum Concentrations

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Listing 16.2.5.1
Serum Concentrations

Age/Sex/ Subject Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units	
12	25/M/Ca	Subject-specific, UB Cigarette	COTININE	02NOV2011/09:10:37	PRE-ADMINISTRATION	529	ng/mL
				02NOV2011/09:12:50	0 MINUTES POST-ADMINISTRATION	547	ng/mL
				02NOV2011/09:15:27	3 MINUTES POST-ADMINISTRATION	543	ng/mL
				02NOV2011/09:17:29	5 MINUTES POST-ADMINISTRATION	534	ng/mL
				02NOV2011/09:20:31	7.5 MINUTES POST-ADMINISTRATION	541	ng/mL
				02NOV2011/09:22:39	10 MINUTES POST-ADMINISTRATION	539	ng/mL
				02NOV2011/09:27:39	15 MINUTES POST-ADMINISTRATION	532	ng/mL
				02NOV2011/09:32:40	20 MINUTES POST-ADMINISTRATION	561	ng/mL
				02NOV2011/09:42:46	30 MINUTES POST-ADMINISTRATION	551	ng/mL
				02NOV2011/09:57:35	45 MINUTES POST-ADMINISTRATION	545	ng/mL
				02NOV2011/10:12:29	60 MINUTES POST-ADMINISTRATION	532	ng/mL
				02NOV2011/10:27:35	75 MINUTES POST-ADMINISTRATION	522	ng/mL
				02NOV2011/10:42:48	90 MINUTES POST-ADMINISTRATION	522	ng/mL
				02NOV2011/11:12:00	120 MINUTES POST-ADMINISTRATION	511	ng/mL
				02NOV2011/11:42:29	150 MINUTES POST-ADMINISTRATION	519	ng/mL
				02NOV2011/12:12:31	180 MINUTES POST-ADMINISTRATION	522	ng/mL

Listing 16.2.5.1
Serum Concentrations

Age/Sex/ Subject Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units	
12	25/M/Ca	Subject-specific, UB Cigarette	NICOTINE	02NOV2011/09:10:37	PRE-ADMINISTRATION	4.62	ng/mL
				02NOV2011/09:12:50	0 MINUTES POST-ADMINISTRATION	5.01	ng/mL
				02NOV2011/09:15:27	3 MINUTES POST-ADMINISTRATION	37.6	ng/mL
				02NOV2011/09:17:29	5 MINUTES POST-ADMINISTRATION	39.3	ng/mL
				02NOV2011/09:20:31	7.5 MINUTES POST-ADMINISTRATION	35.2	ng/mL
				02NOV2011/09:22:39	10 MINUTES POST-ADMINISTRATION	33.7	ng/mL
				02NOV2011/09:27:39	15 MINUTES POST-ADMINISTRATION	29.8	ng/mL
				02NOV2011/09:32:40	20 MINUTES POST-ADMINISTRATION	25.9	ng/mL
				02NOV2011/09:42:46	30 MINUTES POST-ADMINISTRATION	21.1	ng/mL
				02NOV2011/09:57:35	45 MINUTES POST-ADMINISTRATION	18.2	ng/mL
				02NOV2011/10:12:29	60 MINUTES POST-ADMINISTRATION	14.9	ng/mL
				02NOV2011/10:27:35	75 MINUTES POST-ADMINISTRATION	12.8	ng/mL
				02NOV2011/10:42:48	90 MINUTES POST-ADMINISTRATION	11.3	ng/mL
				02NOV2011/11:12:00	120 MINUTES POST-ADMINISTRATION	8.94	ng/mL
				02NOV2011/11:42:29	150 MINUTES POST-ADMINISTRATION	8.21	ng/mL
				02NOV2011/12:12:31	180 MINUTES POST-ADMINISTRATION	7.75	ng/mL
		NICOTINE ADJ	NICOTINE ADJ	02NOV2011/09:12:50	0 MINUTES POST-ADMINISTRATION	0.000	ng/mL
				02NOV2011/09:15:27	3 MINUTES POST-ADMINISTRATION	32.676	ng/mL
				02NOV2011/09:17:29	5 MINUTES POST-ADMINISTRATION	34.433	ng/mL
				02NOV2011/09:20:31	7.5 MINUTES POST-ADMINISTRATION	30.402	ng/mL
				02NOV2011/09:22:39	10 MINUTES POST-ADMINISTRATION	28.971	ng/mL
				02NOV2011/09:27:39	15 MINUTES POST-ADMINISTRATION	25.206	ng/mL
				02NOV2011/09:32:40	20 MINUTES POST-ADMINISTRATION	21.437	ng/mL
				02NOV2011/09:42:46	30 MINUTES POST-ADMINISTRATION	16.887	ng/mL
				02NOV2011/09:57:35	45 MINUTES POST-ADMINISTRATION	14.337	ng/mL
				02NOV2011/10:12:29	60 MINUTES POST-ADMINISTRATION	11.357	ng/mL
				02NOV2011/10:27:35	75 MINUTES POST-ADMINISTRATION	9.551	ng/mL
				02NOV2011/10:42:48	90 MINUTES POST-ADMINISTRATION	8.321	ng/mL
				02NOV2011/11:12:00	120 MINUTES POST-ADMINISTRATION	6.435	ng/mL
				02NOV2011/11:42:29	150 MINUTES POST-ADMINISTRATION	6.104	ng/mL
				02NOV2011/12:12:31	180 MINUTES POST-ADMINISTRATION	5.979	ng/mL

Listing 16.2.5.1
Serum Concentrations

(b) (4)



Listing 16.2.5.1
Serum Concentrations

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Listing 16.2.5.1
Serum Concentrations

(b) (4)



Listing 16.2.5.1
Serum Concentrations

(b) (4)



Listing 16.2.5.1
Serum Concentrations

(b) (4)



Listing 16.2.5.1
Serum Concentrations

Subject	Age/Sex/ Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units
12	25/M/Ca	Camel SNUS	NICOTINE	07DEC2011/08:51:09	PRE-ADMINISTRATION	16.1	ng/mL
				07DEC2011/08:51:37	0 MINUTES POST-ADMINISTRATION	17.5	ng/mL
				07DEC2011/08:54:36	3 MINUTES POST-ADMINISTRATION	16.7	ng/mL
				07DEC2011/08:56:36	5 MINUTES POST-ADMINISTRATION	16.2	ng/mL
				07DEC2011/08:59:06	7.5 MINUTES POST-ADMINISTRATION	16.4	ng/mL
				07DEC2011/09:01:36	10 MINUTES POST-ADMINISTRATION	17.6	ng/mL
				07DEC2011/09:06:37	15 MINUTES POST-ADMINISTRATION	17.8	ng/mL
				07DEC2011/09:12:04	20 MINUTES POST-ADMINISTRATION	18.1	ng/mL
				07DEC2011/09:21:22	30 MINUTES POST-ADMINISTRATION	18.5	ng/mL
				07DEC2011/09:36:25	45 MINUTES POST-ADMINISTRATION	19.2	ng/mL
				07DEC2011/09:51:33	60 MINUTES POST-ADMINISTRATION	16.9	ng/mL
				07DEC2011/10:06:34	75 MINUTES POST-ADMINISTRATION	16.8	ng/mL
				07DEC2011/10:21:32	90 MINUTES POST-ADMINISTRATION	13	ng/mL
				07DEC2011/10:51:37	120 MINUTES POST-ADMINISTRATION	12	ng/mL
				07DEC2011/11:21:45	150 MINUTES POST-ADMINISTRATION	9.27	ng/mL
				07DEC2011/11:51:35	180 MINUTES POST-ADMINISTRATION	9.23	ng/mL
			NICOTINE ADJ	07DEC2011/08:51:37	0 MINUTES POST-ADMINISTRATION	0.000	ng/mL
				07DEC2011/08:54:36	3 MINUTES POST-ADMINISTRATION	0.000	ng/mL
				07DEC2011/08:56:36	5 MINUTES POST-ADMINISTRATION	0.000	ng/mL
				07DEC2011/08:59:06	7.5 MINUTES POST-ADMINISTRATION	0.000	ng/mL
				07DEC2011/09:01:36	10 MINUTES POST-ADMINISTRATION	1.082	ng/mL
				07DEC2011/09:06:37	15 MINUTES POST-ADMINISTRATION	1.752	ng/mL
				07DEC2011/09:12:04	20 MINUTES POST-ADMINISTRATION	2.509	ng/mL
				07DEC2011/09:21:22	30 MINUTES POST-ADMINISTRATION	3.784	ng/mL
				07DEC2011/09:36:25	45 MINUTES POST-ADMINISTRATION	5.706	ng/mL
				07DEC2011/09:51:33	60 MINUTES POST-ADMINISTRATION	4.526	ng/mL
				07DEC2011/10:06:34	75 MINUTES POST-ADMINISTRATION	5.453	ng/mL
				07DEC2011/10:21:32	90 MINUTES POST-ADMINISTRATION	2.594	ng/mL
				07DEC2011/10:51:37	120 MINUTES POST-ADMINISTRATION	3.250	ng/mL
				07DEC2011/11:21:45	150 MINUTES POST-ADMINISTRATION	1.912	ng/mL
				07DEC2011/11:51:35	180 MINUTES POST-ADMINISTRATION	3.043	ng/mL

Listing 16.2.5.1
Serum Concentrations

Age/Sex/ Subject Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units	
13	26/F/Ca	Subject-specific, UB Cigarette	COTININE	03NOV2011/08:51:16	PRE-ADMINISTRATION	69.6	ng/mL
				03NOV2011/08:53:21	0 MINUTES POST-ADMINISTRATION	68.2	ng/mL
				03NOV2011/08:56:19	3 MINUTES POST-ADMINISTRATION	72.3	ng/mL
				03NOV2011/08:58:19	5 MINUTES POST-ADMINISTRATION	70.9	ng/mL
				03NOV2011/09:00:49	7.5 MINUTES POST-ADMINISTRATION	70.8	ng/mL
				03NOV2011/09:08:19	15 MINUTES POST-ADMINISTRATION	72.1	ng/mL
				03NOV2011/09:13:19	20 MINUTES POST-ADMINISTRATION	77.3	ng/mL
				03NOV2011/09:23:19	30 MINUTES POST-ADMINISTRATION	84.6	ng/mL
				03NOV2011/09:38:18	45 MINUTES POST-ADMINISTRATION	79.7	ng/mL
				03NOV2011/09:53:18	60 MINUTES POST-ADMINISTRATION	82.5	ng/mL
				03NOV2011/10:08:18	75 MINUTES POST-ADMINISTRATION	76.4	ng/mL
				03NOV2011/10:23:17	90 MINUTES POST-ADMINISTRATION	76.7	ng/mL
				03NOV2011/10:53:17	120 MINUTES POST-ADMINISTRATION	79.1	ng/mL
				03NOV2011/11:23:17	150 MINUTES POST-ADMINISTRATION	73.5	ng/mL
				03NOV2011/11:53:18	180 MINUTES POST-ADMINISTRATION	70.3	ng/mL
		NICOTINE	NICOTINE	03NOV2011/08:51:16	PRE-ADMINISTRATION	0.555	ng/mL
				03NOV2011/08:53:21	0 MINUTES POST-ADMINISTRATION	0.659	ng/mL
				03NOV2011/08:56:19	3 MINUTES POST-ADMINISTRATION	4.2	ng/mL
				03NOV2011/08:58:19	5 MINUTES POST-ADMINISTRATION	5.08	ng/mL
				03NOV2011/09:00:49	7.5 MINUTES POST-ADMINISTRATION	5.88	ng/mL
				03NOV2011/09:08:19	15 MINUTES POST-ADMINISTRATION	7.14	ng/mL
				03NOV2011/09:13:19	20 MINUTES POST-ADMINISTRATION	7.11	ng/mL
				03NOV2011/09:23:19	30 MINUTES POST-ADMINISTRATION	6.5	ng/mL
				03NOV2011/09:38:18	45 MINUTES POST-ADMINISTRATION	4.25	ng/mL
				03NOV2011/09:53:18	60 MINUTES POST-ADMINISTRATION	3.76	ng/mL
				03NOV2011/10:08:18	75 MINUTES POST-ADMINISTRATION	3.12	ng/mL
				03NOV2011/10:23:17	90 MINUTES POST-ADMINISTRATION	2.55	ng/mL
				03NOV2011/10:53:17	120 MINUTES POST-ADMINISTRATION	2.15	ng/mL
				03NOV2011/11:23:17	150 MINUTES POST-ADMINISTRATION	2.02	ng/mL
				03NOV2011/11:53:18	180 MINUTES POST-ADMINISTRATION	1.57	ng/mL

Listing 16.2.5.1
Serum Concentrations

Age/Sex/ Subject Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units	
13	26/F/Ca	Subject-specific, UB Cigarette	NICOTINE ADJ	03NOV2011/08:53:21	0 MINUTES POST-ADMINISTRATION	0.000	ng/mL
				03NOV2011/08:56:19	3 MINUTES POST-ADMINISTRATION	3.552	ng/mL
				03NOV2011/08:58:19	5 MINUTES POST-ADMINISTRATION	4.440	ng/mL
				03NOV2011/09:00:49	7.5 MINUTES POST-ADMINISTRATION	5.249	ng/mL
				03NOV2011/09:08:19	15 MINUTES POST-ADMINISTRATION	6.536	ng/mL
				03NOV2011/09:13:19	20 MINUTES POST-ADMINISTRATION	6.523	ng/mL
				03NOV2011/09:23:19	30 MINUTES POST-ADMINISTRATION	5.946	ng/mL
				03NOV2011/09:38:18	45 MINUTES POST-ADMINISTRATION	3.742	ng/mL
				03NOV2011/09:53:18	60 MINUTES POST-ADMINISTRATION	3.294	ng/mL
				03NOV2011/10:08:18	75 MINUTES POST-ADMINISTRATION	2.693	ng/mL
				03NOV2011/10:23:17	90 MINUTES POST-ADMINISTRATION	2.158	ng/mL
				03NOV2011/10:53:17	120 MINUTES POST-ADMINISTRATION	1.821	ng/mL
				03NOV2011/11:23:17	150 MINUTES POST-ADMINISTRATION	1.743	ng/mL
				03NOV2011/11:53:18	180 MINUTES POST-ADMINISTRATION	1.337	ng/mL

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Listing 16.2.5.1
Serum Concentrations

(b) (4)



Listing 16.2.5.1
Serum Concentrations

Age/Sex/ Subject Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units	
13	26/F/Ca	Camel SNUS	COTININE	17NOV2011/08:51:21	PRE-ADMINISTRATION	96	ng/mL
				17NOV2011/08:53:09	0 MINUTES POST-ADMINISTRATION	104	ng/mL
				17NOV2011/08:56:10	3 MINUTES POST-ADMINISTRATION	101	ng/mL
				17NOV2011/08:58:07	5 MINUTES POST-ADMINISTRATION	102	ng/mL
				17NOV2011/09:00:39	7.5 MINUTES POST-ADMINISTRATION	97.1	ng/mL
				17NOV2011/09:03:09	10 MINUTES POST-ADMINISTRATION	95.3	ng/mL
				17NOV2011/09:08:07	15 MINUTES POST-ADMINISTRATION	101	ng/mL
				17NOV2011/09:13:09	20 MINUTES POST-ADMINISTRATION	102	ng/mL
				17NOV2011/09:23:09	30 MINUTES POST-ADMINISTRATION	112	ng/mL
				17NOV2011/09:38:10	45 MINUTES POST-ADMINISTRATION	115	ng/mL
				17NOV2011/09:53:08	60 MINUTES POST-ADMINISTRATION	113	ng/mL
				17NOV2011/10:08:10	75 MINUTES POST-ADMINISTRATION	111	ng/mL
				17NOV2011/10:23:09	90 MINUTES POST-ADMINISTRATION	108	ng/mL
				17NOV2011/10:53:08	120 MINUTES POST-ADMINISTRATION	101	ng/mL
				17NOV2011/11:23:07	150 MINUTES POST-ADMINISTRATION	102	ng/mL
				17NOV2011/11:53:06	180 MINUTES POST-ADMINISTRATION	95.3	ng/mL
		NICOTINE	17NOV2011/08:51:21	PRE-ADMINISTRATION	0.871	ng/mL	
			17NOV2011/08:53:09	0 MINUTES POST-ADMINISTRATION	0.734	ng/mL	
			17NOV2011/08:56:10	3 MINUTES POST-ADMINISTRATION	0.934	ng/mL	
			17NOV2011/08:58:07	5 MINUTES POST-ADMINISTRATION	2.14	ng/mL	
			17NOV2011/09:00:39	7.5 MINUTES POST-ADMINISTRATION	3.16	ng/mL	
			17NOV2011/09:03:09	10 MINUTES POST-ADMINISTRATION	3.34	ng/mL	
			17NOV2011/09:08:07	15 MINUTES POST-ADMINISTRATION	3.55	ng/mL	
			17NOV2011/09:13:09	20 MINUTES POST-ADMINISTRATION	3.82	ng/mL	
			17NOV2011/09:23:09	30 MINUTES POST-ADMINISTRATION	4.08	ng/mL	
			17NOV2011/09:38:10	45 MINUTES POST-ADMINISTRATION	3.43	ng/mL	
			17NOV2011/09:53:08	60 MINUTES POST-ADMINISTRATION	2.68	ng/mL	
			17NOV2011/10:08:10	75 MINUTES POST-ADMINISTRATION	2.56	ng/mL	
			17NOV2011/10:23:09	90 MINUTES POST-ADMINISTRATION	2.12	ng/mL	
			17NOV2011/10:53:08	120 MINUTES POST-ADMINISTRATION	1.88	ng/mL	
			17NOV2011/11:23:07	150 MINUTES POST-ADMINISTRATION	1.77	ng/mL	
			17NOV2011/11:53:06	180 MINUTES POST-ADMINISTRATION	1.41	ng/mL	

Listing 16.2.5.1
Serum Concentrations

Subject	Age/Sex/ Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units
13	26/F/Ca	Camel SNUS	NICOTINE ADJ	17NOV2011/08:53:09	0 MINUTES POST-ADMINISTRATION	0.000	ng/mL
				17NOV2011/08:56:10	3 MINUTES POST-ADMINISTRATION	0.213	ng/mL
				17NOV2011/08:58:07	5 MINUTES POST-ADMINISTRATION	1.427	ng/mL
				17NOV2011/09:00:39	7.5 MINUTES POST-ADMINISTRATION	2.457	ng/mL
				17NOV2011/09:03:09	10 MINUTES POST-ADMINISTRATION	2.647	ng/mL
				17NOV2011/09:08:07	15 MINUTES POST-ADMINISTRATION	2.877	ng/mL
				17NOV2011/09:13:09	20 MINUTES POST-ADMINISTRATION	3.166	ng/mL
				17NOV2011/09:23:09	30 MINUTES POST-ADMINISTRATION	3.463	ng/mL
				17NOV2011/09:38:10	45 MINUTES POST-ADMINISTRATION	2.864	ng/mL
				17NOV2011/09:53:08	60 MINUTES POST-ADMINISTRATION	2.161	ng/mL
				17NOV2011/10:08:10	75 MINUTES POST-ADMINISTRATION	2.084	ng/mL
				17NOV2011/10:23:09	90 MINUTES POST-ADMINISTRATION	1.684	ng/mL
				17NOV2011/10:53:08	120 MINUTES POST-ADMINISTRATION	1.513	ng/mL
				17NOV2011/11:23:07	150 MINUTES POST-ADMINISTRATION	1.461	ng/mL
				17NOV2011/11:53:06	180 MINUTES POST-ADMINISTRATION	1.150	ng/mL

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Listing 16.2.5.1
Serum Concentrations

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Listing 16.2.5.1
Serum Concentrations

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Listing 16.2.5.1
Serum Concentrations

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Listing 16.2.5.1
Serum Concentrations

Age/Sex/ Subject Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units	
14	35/F/Ca	Subject-specific, UB Cigarette	COTININE	03NOV2011/08:51:50	PRE-ADMINISTRATION	265	ng/mL
				03NOV2011/08:52:58	0 MINUTES POST-ADMINISTRATION	247	ng/mL
				03NOV2011/08:55:57	3 MINUTES POST-ADMINISTRATION	250	ng/mL
				03NOV2011/08:57:57	5 MINUTES POST-ADMINISTRATION	251	ng/mL
				03NOV2011/09:00:27	7.5 MINUTES POST-ADMINISTRATION	272	ng/mL
				03NOV2011/09:02:57	10 MINUTES POST-ADMINISTRATION	270	ng/mL
				03NOV2011/09:07:58	15 MINUTES POST-ADMINISTRATION	271	ng/mL
				03NOV2011/09:12:57	20 MINUTES POST-ADMINISTRATION	274	ng/mL
				03NOV2011/09:22:57	30 MINUTES POST-ADMINISTRATION	272	ng/mL
				03NOV2011/09:37:57	45 MINUTES POST-ADMINISTRATION	272	ng/mL
				03NOV2011/09:52:57	60 MINUTES POST-ADMINISTRATION	272	ng/mL
				03NOV2011/10:11:04	75 MINUTES POST-ADMINISTRATION	268	ng/mL
				03NOV2011/10:22:56	90 MINUTES POST-ADMINISTRATION	269	ng/mL
				03NOV2011/10:53:04	120 MINUTES POST-ADMINISTRATION	276	ng/mL
				03NOV2011/11:22:56	150 MINUTES POST-ADMINISTRATION	254	ng/mL
				03NOV2011/11:52:56	180 MINUTES POST-ADMINISTRATION	251	ng/mL

Listing 16.2.5.1
Serum Concentrations

Age/Sex/ Subject Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units	
14	35/F/Ca	Subject-specific, UB Cigarette	NICOTINE	03NOV2011/08:51:50	PRE-ADMINISTRATION	1.07	ng/mL
				03NOV2011/08:52:58	0 MINUTES POST-ADMINISTRATION	0.884	ng/mL
				03NOV2011/08:55:57	3 MINUTES POST-ADMINISTRATION	3.46	ng/mL
				03NOV2011/08:57:57	5 MINUTES POST-ADMINISTRATION	6.14	ng/mL
				03NOV2011/09:00:27	7.5 MINUTES POST-ADMINISTRATION	7.94	ng/mL
				03NOV2011/09:02:57	10 MINUTES POST-ADMINISTRATION	10.5	ng/mL
				03NOV2011/09:07:58	15 MINUTES POST-ADMINISTRATION	9.75	ng/mL
				03NOV2011/09:12:57	20 MINUTES POST-ADMINISTRATION	9.75	ng/mL
				03NOV2011/09:22:57	30 MINUTES POST-ADMINISTRATION	9.83	ng/mL
				03NOV2011/09:37:57	45 MINUTES POST-ADMINISTRATION	8.81	ng/mL
				03NOV2011/09:52:57	60 MINUTES POST-ADMINISTRATION	8.1	ng/mL
				03NOV2011/10:11:04	75 MINUTES POST-ADMINISTRATION	7.51	ng/mL
				03NOV2011/10:22:56	90 MINUTES POST-ADMINISTRATION	6.51	ng/mL
				03NOV2011/10:53:04	120 MINUTES POST-ADMINISTRATION	5.05	ng/mL
				03NOV2011/11:22:56	150 MINUTES POST-ADMINISTRATION	4.91	ng/mL
				03NOV2011/11:52:56	180 MINUTES POST-ADMINISTRATION	4.24	ng/mL
		NICOTINE ADJ	03NOV2011/08:52:58	0 MINUTES POST-ADMINISTRATION	0.000	ng/mL	
			03NOV2011/08:55:57	3 MINUTES POST-ADMINISTRATION	2.591	ng/mL	
			03NOV2011/08:57:57	5 MINUTES POST-ADMINISTRATION	5.281	ng/mL	
			03NOV2011/09:00:27	7.5 MINUTES POST-ADMINISTRATION	7.093	ng/mL	
			03NOV2011/09:02:57	10 MINUTES POST-ADMINISTRATION	9.666	ng/mL	
			03NOV2011/09:07:58	15 MINUTES POST-ADMINISTRATION	8.939	ng/mL	
			03NOV2011/09:12:57	20 MINUTES POST-ADMINISTRATION	8.962	ng/mL	
			03NOV2011/09:22:57	30 MINUTES POST-ADMINISTRATION	9.087	ng/mL	
			03NOV2011/09:37:57	45 MINUTES POST-ADMINISTRATION	8.128	ng/mL	
			03NOV2011/09:52:57	60 MINUTES POST-ADMINISTRATION	7.475	ng/mL	
			03NOV2011/10:11:04	75 MINUTES POST-ADMINISTRATION	6.937	ng/mL	
			03NOV2011/10:22:56	90 MINUTES POST-ADMINISTRATION	5.984	ng/mL	
			03NOV2011/10:53:04	120 MINUTES POST-ADMINISTRATION	4.608	ng/mL	
			03NOV2011/11:22:56	150 MINUTES POST-ADMINISTRATION	4.538	ng/mL	
			03NOV2011/11:52:56	180 MINUTES POST-ADMINISTRATION	3.927	ng/mL	

Listing 16.2.5.1
Serum Concentrations

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Listing 16.2.5.1
Serum Concentrations

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Listing 16.2.5.1
Serum Concentrations

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Listing 16.2.5.1
Serum Concentrations

Subject	Age/Sex/ Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units
14	35/F/Ca	Camel SNUS	COTININE	01DEC2011/09:00:35	PRE-ADMINISTRATION	204	ng/mL
				01DEC2011/09:00:43	0 MINUTES POST-ADMINISTRATION	195	ng/mL
				01DEC2011/09:03:43	3 MINUTES POST-ADMINISTRATION	198	ng/mL
				01DEC2011/09:05:43	5 MINUTES POST-ADMINISTRATION	206	ng/mL
				01DEC2011/09:08:13	7.5 MINUTES POST-ADMINISTRATION	191	ng/mL
				01DEC2011/09:10:43	10 MINUTES POST-ADMINISTRATION	199	ng/mL
				01DEC2011/09:15:43	15 MINUTES POST-ADMINISTRATION	194	ng/mL
				01DEC2011/09:20:43	20 MINUTES POST-ADMINISTRATION	204	ng/mL
				01DEC2011/09:30:43	30 MINUTES POST-ADMINISTRATION	200	ng/mL
				01DEC2011/09:45:44	45 MINUTES POST-ADMINISTRATION	209	ng/mL
				01DEC2011/10:00:43	60 MINUTES POST-ADMINISTRATION	193	ng/mL
				01DEC2011/10:15:43	75 MINUTES POST-ADMINISTRATION	198	ng/mL
				01DEC2011/10:30:43	90 MINUTES POST-ADMINISTRATION	199	ng/mL
				01DEC2011/11:00:41	120 MINUTES POST-ADMINISTRATION	196	ng/mL
				01DEC2011/11:30:41	150 MINUTES POST-ADMINISTRATION	192	ng/mL
				01DEC2011/12:00:42	180 MINUTES POST-ADMINISTRATION	185	ng/mL
			NICOTINE	01DEC2011/09:00:35	PRE-ADMINISTRATION	0.695	ng/mL
				01DEC2011/09:00:43	0 MINUTES POST-ADMINISTRATION	0.558	ng/mL
				01DEC2011/09:03:43	3 MINUTES POST-ADMINISTRATION	1.19	ng/mL
				01DEC2011/09:05:43	5 MINUTES POST-ADMINISTRATION	2.26	ng/mL
				01DEC2011/09:08:13	7.5 MINUTES POST-ADMINISTRATION	1.81	ng/mL
				01DEC2011/09:10:43	10 MINUTES POST-ADMINISTRATION	1.85	ng/mL
				01DEC2011/09:15:43	15 MINUTES POST-ADMINISTRATION	2.32	ng/mL
				01DEC2011/09:20:43	20 MINUTES POST-ADMINISTRATION	2.29	ng/mL
				01DEC2011/09:30:43	30 MINUTES POST-ADMINISTRATION	2.19	ng/mL
				01DEC2011/09:45:44	45 MINUTES POST-ADMINISTRATION	2.42	ng/mL
				01DEC2011/10:00:43	60 MINUTES POST-ADMINISTRATION	1.97	ng/mL
				01DEC2011/10:15:43	75 MINUTES POST-ADMINISTRATION	1.83	ng/mL
				01DEC2011/10:30:43	90 MINUTES POST-ADMINISTRATION	1.63	ng/mL
				01DEC2011/11:00:41	120 MINUTES POST-ADMINISTRATION	1.76	ng/mL
				01DEC2011/11:30:41	150 MINUTES POST-ADMINISTRATION	1.57	ng/mL
				01DEC2011/12:00:42	180 MINUTES POST-ADMINISTRATION	1.46	ng/mL

Listing 16.2.5.1
Serum Concentrations

Subject	Age/Sex/ Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units
14	35/F/Ca	Camel SNUS	NICOTINE ADJ	01DEC2011/09:00:43	0 MINUTES POST-ADMINISTRATION	0.000	ng/mL
				01DEC2011/09:03:43	3 MINUTES POST-ADMINISTRATION	0.642	ng/mL
				01DEC2011/09:05:43	5 MINUTES POST-ADMINISTRATION	1.718	ng/mL
				01DEC2011/09:08:13	7.5 MINUTES POST-ADMINISTRATION	1.276	ng/mL
				01DEC2011/09:10:43	10 MINUTES POST-ADMINISTRATION	1.323	ng/mL
				01DEC2011/09:15:43	15 MINUTES POST-ADMINISTRATION	1.808	ng/mL
				01DEC2011/09:20:43	20 MINUTES POST-ADMINISTRATION	1.793	ng/mL
				01DEC2011/09:30:43	30 MINUTES POST-ADMINISTRATION	1.721	ng/mL
				01DEC2011/09:45:44	45 MINUTES POST-ADMINISTRATION	1.990	ng/mL
				01DEC2011/10:00:43	60 MINUTES POST-ADMINISTRATION	1.575	ng/mL
				01DEC2011/10:15:43	75 MINUTES POST-ADMINISTRATION	1.468	ng/mL
				01DEC2011/10:30:43	90 MINUTES POST-ADMINISTRATION	1.298	ng/mL
				01DEC2011/11:00:41	120 MINUTES POST-ADMINISTRATION	1.481	ng/mL
				01DEC2011/11:30:41	150 MINUTES POST-ADMINISTRATION	1.335	ng/mL
				01DEC2011/12:00:42	180 MINUTES POST-ADMINISTRATION	1.263	ng/mL

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Listing 16.2.5.1
Serum Concentrations

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Listing 16.2.5.1
Serum Concentrations

	Age/Sex/ Subject Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units
15	26/M/Ca	Subject-specific, UB Cigarette	COTININE	03NOV2011/08:54:54	PRE-ADMINISTRATION	203	ng/mL
				03NOV2011/08:56:31	0 MINUTES POST-ADMINISTRATION	193	ng/mL
				03NOV2011/08:59:26	3 MINUTES POST-ADMINISTRATION	194	ng/mL
				03NOV2011/09:01:40	5 MINUTES POST-ADMINISTRATION	196	ng/mL
				03NOV2011/09:03:57	7.5 MINUTES POST-ADMINISTRATION	212	ng/mL
				03NOV2011/09:06:27	10 MINUTES POST-ADMINISTRATION	202	ng/mL
				03NOV2011/09:11:27	15 MINUTES POST-ADMINISTRATION	207	ng/mL
				03NOV2011/09:16:27	20 MINUTES POST-ADMINISTRATION	209	ng/mL
				03NOV2011/09:26:29	30 MINUTES POST-ADMINISTRATION	212	ng/mL
				03NOV2011/09:41:26	45 MINUTES POST-ADMINISTRATION	214	ng/mL
				03NOV2011/09:56:26	60 MINUTES POST-ADMINISTRATION	212	ng/mL
				03NOV2011/10:11:27	75 MINUTES POST-ADMINISTRATION	211	ng/mL
				03NOV2011/10:26:26	90 MINUTES POST-ADMINISTRATION	212	ng/mL
				03NOV2011/10:56:27	120 MINUTES POST-ADMINISTRATION	209	ng/mL
				03NOV2011/11:26:27	150 MINUTES POST-ADMINISTRATION	206	ng/mL
				03NOV2011/11:56:28	180 MINUTES POST-ADMINISTRATION	213	ng/mL
		NICOTINE	NICOTINE	03NOV2011/08:54:54	PRE-ADMINISTRATION	0.955	ng/mL
				03NOV2011/08:56:31	0 MINUTES POST-ADMINISTRATION	0.746	ng/mL
				03NOV2011/08:59:26	3 MINUTES POST-ADMINISTRATION	9.34	ng/mL
				03NOV2011/09:01:40	5 MINUTES POST-ADMINISTRATION	11.3	ng/mL
				03NOV2011/09:03:57	7.5 MINUTES POST-ADMINISTRATION	13.5	ng/mL
				03NOV2011/09:06:27	10 MINUTES POST-ADMINISTRATION	18	ng/mL
				03NOV2011/09:11:27	15 MINUTES POST-ADMINISTRATION	13.8	ng/mL
				03NOV2011/09:16:27	20 MINUTES POST-ADMINISTRATION	12.7	ng/mL
				03NOV2011/09:26:29	30 MINUTES POST-ADMINISTRATION	10.4	ng/mL
				03NOV2011/09:41:26	45 MINUTES POST-ADMINISTRATION	8.97	ng/mL
				03NOV2011/09:56:26	60 MINUTES POST-ADMINISTRATION	8.15	ng/mL
				03NOV2011/10:11:27	75 MINUTES POST-ADMINISTRATION	6.73	ng/mL
				03NOV2011/10:26:26	90 MINUTES POST-ADMINISTRATION	6.68	ng/mL
				03NOV2011/10:56:27	120 MINUTES POST-ADMINISTRATION	6.13	ng/mL
				03NOV2011/11:26:27	150 MINUTES POST-ADMINISTRATION	4.93	ng/mL
				03NOV2011/11:56:28	180 MINUTES POST-ADMINISTRATION	4.77	ng/mL

Listing 16.2.5.1
Serum Concentrations

Age/Sex/ Subject Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units
15	26/M/Ca Subject-specific, UB Cigarette	NICOTINE ADJ	03NOV2011/08:56:31	0 MINUTES POST-ADMINISTRATION	0.000	ng/mL
			03NOV2011/08:59:26	3 MINUTES POST-ADMINISTRATION	8.607	ng/mL
			03NOV2011/09:01:40	5 MINUTES POST-ADMINISTRATION	10.575	ng/mL
			03NOV2011/09:03:57	7.5 MINUTES POST-ADMINISTRATION	12.786	ng/mL
			03NOV2011/09:06:27	10 MINUTES POST-ADMINISTRATION	17.296	ng/mL
			03NOV2011/09:11:27	15 MINUTES POST-ADMINISTRATION	13.116	ng/mL
			03NOV2011/09:16:27	20 MINUTES POST-ADMINISTRATION	12.035	ng/mL
			03NOV2011/09:26:29	30 MINUTES POST-ADMINISTRATION	9.773	ng/mL
			03NOV2011/09:41:26	45 MINUTES POST-ADMINISTRATION	8.395	ng/mL
			03NOV2011/09:56:26	60 MINUTES POST-ADMINISTRATION	7.622	ng/mL
			03NOV2011/10:11:27	75 MINUTES POST-ADMINISTRATION	6.246	ng/mL
			03NOV2011/10:26:26	90 MINUTES POST-ADMINISTRATION	6.236	ng/mL
			03NOV2011/10:56:27	120 MINUTES POST-ADMINISTRATION	5.757	ng/mL
			03NOV2011/11:26:27	150 MINUTES POST-ADMINISTRATION	4.616	ng/mL
			03NOV2011/11:56:28	180 MINUTES POST-ADMINISTRATION	4.506	ng/mL
	Camel SNUS	COTININE	10NOV2011/08:46:44	PRE-ADMINISTRATION	260	ng/mL
			10NOV2011/08:47:40	0 MINUTES POST-ADMINISTRATION	264	ng/mL
			10NOV2011/08:50:41	3 MINUTES POST-ADMINISTRATION	260	ng/mL
			10NOV2011/08:52:41	5 MINUTES POST-ADMINISTRATION	260	ng/mL
			10NOV2011/08:55:11	7.5 MINUTES POST-ADMINISTRATION	261	ng/mL
			10NOV2011/08:57:41	10 MINUTES POST-ADMINISTRATION	265	ng/mL
			10NOV2011/09:02:40	15 MINUTES POST-ADMINISTRATION	271	ng/mL
			10NOV2011/09:07:41	20 MINUTES POST-ADMINISTRATION	264	ng/mL
			10NOV2011/09:17:40	30 MINUTES POST-ADMINISTRATION	264	ng/mL
			10NOV2011/09:32:41	45 MINUTES POST-ADMINISTRATION	266	ng/mL
			10NOV2011/09:47:41	60 MINUTES POST-ADMINISTRATION	266	ng/mL
			10NOV2011/10:02:41	75 MINUTES POST-ADMINISTRATION	254	ng/mL
			10NOV2011/10:17:41	90 MINUTES POST-ADMINISTRATION	255	ng/mL
			10NOV2011/10:47:46	120 MINUTES POST-ADMINISTRATION	252	ng/mL
			10NOV2011/11:17:45	150 MINUTES POST-ADMINISTRATION	241	ng/mL
			10NOV2011/11:47:45	180 MINUTES POST-ADMINISTRATION	241	ng/mL

Listing 16.2.5.1
Serum Concentrations

Subject	Age/Sex/ Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units
15	26/M/Ca	Camel SNUS	NICOTINE	10NOV2011/08:46:44	PRE-ADMINISTRATION	3.92	ng/mL
				10NOV2011/08:47:40	0 MINUTES POST-ADMINISTRATION	3.52	ng/mL
				10NOV2011/08:50:41	3 MINUTES POST-ADMINISTRATION	4.45	ng/mL
				10NOV2011/08:52:41	5 MINUTES POST-ADMINISTRATION	5.92	ng/mL
				10NOV2011/08:55:11	7.5 MINUTES POST-ADMINISTRATION	6.35	ng/mL
				10NOV2011/08:57:41	10 MINUTES POST-ADMINISTRATION	6.72	ng/mL
				10NOV2011/09:02:40	15 MINUTES POST-ADMINISTRATION	7.43	ng/mL
				10NOV2011/09:07:41	20 MINUTES POST-ADMINISTRATION	6.71	ng/mL
				10NOV2011/09:17:40	30 MINUTES POST-ADMINISTRATION	8.03	ng/mL
				10NOV2011/09:32:41	45 MINUTES POST-ADMINISTRATION	8.18	ng/mL
				10NOV2011/09:47:41	60 MINUTES POST-ADMINISTRATION	6.68	ng/mL
				10NOV2011/10:02:41	75 MINUTES POST-ADMINISTRATION	6.18	ng/mL
				10NOV2011/10:17:41	90 MINUTES POST-ADMINISTRATION	5.74	ng/mL
				10NOV2011/10:47:46	120 MINUTES POST-ADMINISTRATION	5.03	ng/mL
				10NOV2011/11:17:45	150 MINUTES POST-ADMINISTRATION	4.79	ng/mL
				10NOV2011/11:47:45	180 MINUTES POST-ADMINISTRATION	4.18	ng/mL
			NICOTINE ADJ	10NOV2011/08:47:40	0 MINUTES POST-ADMINISTRATION	0.000	ng/mL
				10NOV2011/08:50:41	3 MINUTES POST-ADMINISTRATION	0.990	ng/mL
				10NOV2011/08:52:41	5 MINUTES POST-ADMINISTRATION	2.500	ng/mL
				10NOV2011/08:55:11	7.5 MINUTES POST-ADMINISTRATION	2.979	ng/mL
				10NOV2011/08:57:41	10 MINUTES POST-ADMINISTRATION	3.398	ng/mL
				10NOV2011/09:02:40	15 MINUTES POST-ADMINISTRATION	4.202	ng/mL
				10NOV2011/09:07:41	20 MINUTES POST-ADMINISTRATION	3.574	ng/mL
				10NOV2011/09:17:40	30 MINUTES POST-ADMINISTRATION	5.070	ng/mL
				10NOV2011/09:32:41	45 MINUTES POST-ADMINISTRATION	5.466	ng/mL
				10NOV2011/09:47:41	60 MINUTES POST-ADMINISTRATION	4.191	ng/mL
				10NOV2011/10:02:41	75 MINUTES POST-ADMINISTRATION	3.898	ng/mL
				10NOV2011/10:17:41	90 MINUTES POST-ADMINISTRATION	3.647	ng/mL
				10NOV2011/10:47:46	120 MINUTES POST-ADMINISTRATION	3.270	ng/mL
				10NOV2011/11:17:45	150 MINUTES POST-ADMINISTRATION	3.310	ng/mL
				10NOV2011/11:47:45	180 MINUTES POST-ADMINISTRATION	2.935	ng/mL

Listing 16.2.5.1
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Listing 16.2.5.1
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Listing 16.2.5.1
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Listing 16.2.5.1
Serum Concentrations

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Listing 16.2.5.1
Serum Concentrations

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Listing 16.2.5.1
Serum Concentrations

Age/Sex/ Subject Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units	
16	53/M/Ca	Subject-specific, UB Cigarette	COTININE	03NOV2011/08:54:33	PRE-ADMINISTRATION	163	ng/mL
				03NOV2011/08:55:34	0 MINUTES POST-ADMINISTRATION	175	ng/mL
				03NOV2011/08:58:33	3 MINUTES POST-ADMINISTRATION	177	ng/mL
				03NOV2011/09:00:39	5 MINUTES POST-ADMINISTRATION	178	ng/mL
				03NOV2011/09:03:05	7.5 MINUTES POST-ADMINISTRATION	182	ng/mL
				03NOV2011/09:05:33	10 MINUTES POST-ADMINISTRATION	183	ng/mL
				03NOV2011/09:10:33	15 MINUTES POST-ADMINISTRATION	178	ng/mL
				03NOV2011/09:15:34	20 MINUTES POST-ADMINISTRATION	174	ng/mL
				03NOV2011/09:25:31	30 MINUTES POST-ADMINISTRATION	179	ng/mL
				03NOV2011/09:40:09	45 MINUTES POST-ADMINISTRATION	180	ng/mL
				03NOV2011/09:55:07	60 MINUTES POST-ADMINISTRATION	191	ng/mL
				03NOV2011/10:10:10	75 MINUTES POST-ADMINISTRATION	187	ng/mL
				03NOV2011/10:25:20	90 MINUTES POST-ADMINISTRATION	178	ng/mL
				03NOV2011/10:54:27	120 MINUTES POST-ADMINISTRATION	176	ng/mL
				03NOV2011/11:24:26	150 MINUTES POST-ADMINISTRATION	187	ng/mL
				03NOV2011/11:54:29	180 MINUTES POST-ADMINISTRATION	170	ng/mL

Listing 16.2.5.1
Serum Concentrations

Age/Sex/ Subject Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units	
16	53/M/Ca	Subject-specific, UB Cigarette	NICOTINE	03NOV2011/08:54:33	PRE-ADMINISTRATION	1.16	ng/mL
				03NOV2011/08:55:34	0 MINUTES POST-ADMINISTRATION	1.25	ng/mL
				03NOV2011/08:58:33	3 MINUTES POST-ADMINISTRATION	15.2	ng/mL
				03NOV2011/09:00:39	5 MINUTES POST-ADMINISTRATION	22.6	ng/mL
				03NOV2011/09:03:05	7.5 MINUTES POST-ADMINISTRATION	18.6	ng/mL
				03NOV2011/09:05:33	10 MINUTES POST-ADMINISTRATION	14.2	ng/mL
				03NOV2011/09:10:33	15 MINUTES POST-ADMINISTRATION	11.6	ng/mL
				03NOV2011/09:15:34	20 MINUTES POST-ADMINISTRATION	11.2	ng/mL
				03NOV2011/09:25:31	30 MINUTES POST-ADMINISTRATION	8.32	ng/mL
				03NOV2011/09:40:09	45 MINUTES POST-ADMINISTRATION	7.17	ng/mL
				03NOV2011/09:55:07	60 MINUTES POST-ADMINISTRATION	6.79	ng/mL
				03NOV2011/10:10:10	75 MINUTES POST-ADMINISTRATION	5.72	ng/mL
				03NOV2011/10:25:20	90 MINUTES POST-ADMINISTRATION	5.76	ng/mL
				03NOV2011/10:54:27	120 MINUTES POST-ADMINISTRATION	4.55	ng/mL
				03NOV2011/11:24:26	150 MINUTES POST-ADMINISTRATION	4.53	ng/mL
				03NOV2011/11:54:29	180 MINUTES POST-ADMINISTRATION	2.9	ng/mL
		NICOTINE ADJ	03NOV2011/08:55:34	0 MINUTES POST-ADMINISTRATION	0.000	ng/mL	
			03NOV2011/08:58:33	3 MINUTES POST-ADMINISTRATION	13.971	ng/mL	
			03NOV2011/09:00:39	5 MINUTES POST-ADMINISTRATION	21.386	ng/mL	
			03NOV2011/09:03:05	7.5 MINUTES POST-ADMINISTRATION	17.403	ng/mL	
			03NOV2011/09:05:33	10 MINUTES POST-ADMINISTRATION	13.020	ng/mL	
			03NOV2011/09:10:33	15 MINUTES POST-ADMINISTRATION	10.454	ng/mL	
			03NOV2011/09:15:34	20 MINUTES POST-ADMINISTRATION	10.086	ng/mL	
			03NOV2011/09:25:31	30 MINUTES POST-ADMINISTRATION	7.269	ng/mL	
			03NOV2011/09:40:09	45 MINUTES POST-ADMINISTRATION	6.206	ng/mL	
			03NOV2011/09:55:07	60 MINUTES POST-ADMINISTRATION	5.906	ng/mL	
			03NOV2011/10:10:10	75 MINUTES POST-ADMINISTRATION	4.909	ng/mL	
			03NOV2011/10:25:20	90 MINUTES POST-ADMINISTRATION	5.017	ng/mL	
			03NOV2011/10:54:27	120 MINUTES POST-ADMINISTRATION	3.925	ng/mL	
			03NOV2011/11:24:26	150 MINUTES POST-ADMINISTRATION	4.004	ng/mL	
			03NOV2011/11:54:29	180 MINUTES POST-ADMINISTRATION	2.458	ng/mL	

Listing 16.2.5.1
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Listing 16.2.5.1
Serum Concentrations

Subject	Age/Sex/ Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units
16	53/M/Ca	Camel SNUS	NICOTINE	08DEC2011/08:42:46	PRE-ADMINISTRATION	1.81	ng/mL
				08DEC2011/08:43:05	0 MINUTES POST-ADMINISTRATION	1.74	ng/mL
				08DEC2011/08:46:04	3 MINUTES POST-ADMINISTRATION	1.79	ng/mL
				08DEC2011/08:48:04	5 MINUTES POST-ADMINISTRATION	2.27	ng/mL
				08DEC2011/08:50:35	7.5 MINUTES POST-ADMINISTRATION	2.68	ng/mL
				08DEC2011/08:53:04	10 MINUTES POST-ADMINISTRATION	3.19	ng/mL
				08DEC2011/08:58:06	15 MINUTES POST-ADMINISTRATION	4.2	ng/mL
				08DEC2011/09:03:04	20 MINUTES POST-ADMINISTRATION	5	ng/mL
				08DEC2011/09:13:04	30 MINUTES POST-ADMINISTRATION	7.15	ng/mL
				08DEC2011/09:28:06	45 MINUTES POST-ADMINISTRATION	10.6	ng/mL
				08DEC2011/09:43:05	60 MINUTES POST-ADMINISTRATION	8.45	ng/mL
				08DEC2011/09:58:05	75 MINUTES POST-ADMINISTRATION	7.23	ng/mL
				08DEC2011/10:13:08	90 MINUTES POST-ADMINISTRATION	5.7	ng/mL
				08DEC2011/10:43:05	120 MINUTES POST-ADMINISTRATION	5.94	ng/mL
				08DEC2011/11:13:07	150 MINUTES POST-ADMINISTRATION	5.18	ng/mL
				08DEC2011/11:43:07	180 MINUTES POST-ADMINISTRATION	3.55	ng/mL
			NICOTINE ADJ	08DEC2011/08:43:05	0 MINUTES POST-ADMINISTRATION	0.000	ng/mL
				08DEC2011/08:46:04	3 MINUTES POST-ADMINISTRATION	0.080	ng/mL
				08DEC2011/08:48:04	5 MINUTES POST-ADMINISTRATION	0.580	ng/mL
				08DEC2011/08:50:35	7.5 MINUTES POST-ADMINISTRATION	1.014	ng/mL
				08DEC2011/08:53:04	10 MINUTES POST-ADMINISTRATION	1.548	ng/mL
				08DEC2011/08:58:06	15 MINUTES POST-ADMINISTRATION	2.604	ng/mL
				08DEC2011/09:03:04	20 MINUTES POST-ADMINISTRATION	3.450	ng/mL
				08DEC2011/09:13:04	30 MINUTES POST-ADMINISTRATION	5.687	ng/mL
				08DEC2011/09:28:06	45 MINUTES POST-ADMINISTRATION	9.258	ng/mL
				08DEC2011/09:43:05	60 MINUTES POST-ADMINISTRATION	7.220	ng/mL
				08DEC2011/09:58:05	75 MINUTES POST-ADMINISTRATION	6.102	ng/mL
				08DEC2011/10:13:08	90 MINUTES POST-ADMINISTRATION	4.665	ng/mL
				08DEC2011/10:43:05	120 MINUTES POST-ADMINISTRATION	5.070	ng/mL
				08DEC2011/11:13:07	150 MINUTES POST-ADMINISTRATION	4.448	ng/mL
				08DEC2011/11:43:07	180 MINUTES POST-ADMINISTRATION	2.935	ng/mL

Listing 16.2.5.1
Serum Concentrations

Age/Sex/ Subject Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units	
17	29/M/Ca	Subject-specific, UB Cigarette	COTININE	15NOV2011/09:51:41	PRE-ADMINISTRATION	204	ng/mL
				15NOV2011/09:53:36	0 MINUTES POST-ADMINISTRATION	219	ng/mL
				15NOV2011/09:56:32	3 MINUTES POST-ADMINISTRATION	211	ng/mL
				15NOV2011/09:58:32	5 MINUTES POST-ADMINISTRATION	214	ng/mL
				15NOV2011/10:01:02	7.5 MINUTES POST-ADMINISTRATION	213	ng/mL
				15NOV2011/10:03:32	10 MINUTES POST-ADMINISTRATION	220	ng/mL
				15NOV2011/10:08:32	15 MINUTES POST-ADMINISTRATION	215	ng/mL
				15NOV2011/10:13:33	20 MINUTES POST-ADMINISTRATION	229	ng/mL
				15NOV2011/10:23:32	30 MINUTES POST-ADMINISTRATION	222	ng/mL
				15NOV2011/10:38:33	45 MINUTES POST-ADMINISTRATION	236	ng/mL
				15NOV2011/10:53:32	60 MINUTES POST-ADMINISTRATION	218	ng/mL
				15NOV2011/11:08:32	75 MINUTES POST-ADMINISTRATION	206	ng/mL
				15NOV2011/11:23:36	90 MINUTES POST-ADMINISTRATION	209	ng/mL
				15NOV2011/11:53:29	120 MINUTES POST-ADMINISTRATION	209	ng/mL
				15NOV2011/12:23:27	150 MINUTES POST-ADMINISTRATION	206	ng/mL
				15NOV2011/12:53:27	180 MINUTES POST-ADMINISTRATION	205	ng/mL
		NICOTINE	NICOTINE	15NOV2011/09:51:41	PRE-ADMINISTRATION	1.29	ng/mL
				15NOV2011/09:53:36	0 MINUTES POST-ADMINISTRATION	1.54	ng/mL
				15NOV2011/09:56:32	3 MINUTES POST-ADMINISTRATION	13.5	ng/mL
				15NOV2011/09:58:32	5 MINUTES POST-ADMINISTRATION	10.1	ng/mL
				15NOV2011/10:01:02	7.5 MINUTES POST-ADMINISTRATION	12	ng/mL
				15NOV2011/10:03:32	10 MINUTES POST-ADMINISTRATION	15.7	ng/mL
				15NOV2011/10:08:32	15 MINUTES POST-ADMINISTRATION	11.3	ng/mL
				15NOV2011/10:13:33	20 MINUTES POST-ADMINISTRATION	10.7	ng/mL
				15NOV2011/10:23:32	30 MINUTES POST-ADMINISTRATION	9.33	ng/mL
				15NOV2011/10:38:33	45 MINUTES POST-ADMINISTRATION	6.3	ng/mL
				15NOV2011/10:53:32	60 MINUTES POST-ADMINISTRATION	5.52	ng/mL
				15NOV2011/11:08:32	75 MINUTES POST-ADMINISTRATION	4.88	ng/mL
				15NOV2011/11:23:36	90 MINUTES POST-ADMINISTRATION	4.07	ng/mL
				15NOV2011/11:53:29	120 MINUTES POST-ADMINISTRATION	3.66	ng/mL
				15NOV2011/12:23:27	150 MINUTES POST-ADMINISTRATION	2.77	ng/mL
				15NOV2011/12:53:27	180 MINUTES POST-ADMINISTRATION	2.56	ng/mL

Listing 16.2.5.1
Serum Concentrations

Subject	Age/Sex/ Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units
17	29/M/Ca	Subject-specific, UB Cigarette	NICOTINE ADJ	15NOV2011/09:53:36	0 MINUTES POST-ADMINISTRATION	0.000	ng/mL
				15NOV2011/09:56:32	3 MINUTES POST-ADMINISTRATION	11.986	ng/mL
				15NOV2011/09:58:32	5 MINUTES POST-ADMINISTRATION	8.604	ng/mL
				15NOV2011/10:01:02	7.5 MINUTES POST-ADMINISTRATION	10.525	ng/mL
				15NOV2011/10:03:32	10 MINUTES POST-ADMINISTRATION	14.246	ng/mL
				15NOV2011/10:08:32	15 MINUTES POST-ADMINISTRATION	9.888	ng/mL
				15NOV2011/10:13:33	20 MINUTES POST-ADMINISTRATION	9.328	ng/mL
				15NOV2011/10:23:32	30 MINUTES POST-ADMINISTRATION	8.035	ng/mL
				15NOV2011/10:38:33	45 MINUTES POST-ADMINISTRATION	5.112	ng/mL
				15NOV2011/10:53:32	60 MINUTES POST-ADMINISTRATION	4.431	ng/mL
				15NOV2011/11:08:32	75 MINUTES POST-ADMINISTRATION	3.881	ng/mL
				15NOV2011/11:23:36	90 MINUTES POST-ADMINISTRATION	3.154	ng/mL
				15NOV2011/11:53:29	120 MINUTES POST-ADMINISTRATION	2.890	ng/mL
				15NOV2011/12:23:27	150 MINUTES POST-ADMINISTRATION	2.123	ng/mL
				15NOV2011/12:53:27	180 MINUTES POST-ADMINISTRATION	2.016	ng/mL

(b) (4)

Listing 16.2.5.1
Serum Concentrations

(b) (4)



Listing 16.2.5.1
Serum Concentrations

(b) (4)



Listing 16.2.5.1
Serum Concentrations

(b) (4)



Listing 16.2.5.1
Serum Concentrations

Subject	Age/Sex/ Race	Product	Analyte	Collection Date/Time	Scheduled Time Point	Concen- tration	Units
17	29/M/Ca	Camel SNUS	NICOTINE	14DEC2011/08:38:27	PRE-ADMINISTRATION	1.22	ng/mL
				14DEC2011/08:39:04	0 MINUTES POST-ADMINISTRATION	1.15	ng/mL
				14DEC2011/08:42:04	3 MINUTES POST-ADMINISTRATION	1.21	ng/mL
				14DEC2011/08:44:07	5 MINUTES POST-ADMINISTRATION	1.7	ng/mL
				14DEC2011/08:46:35	7.5 MINUTES POST-ADMINISTRATION	2.03	ng/mL
				14DEC2011/08:49:03	10 MINUTES POST-ADMINISTRATION	2.12	ng/mL
				14DEC2011/08:54:04	15 MINUTES POST-ADMINISTRATION	2.42	ng/mL
				14DEC2011/08:59:05	20 MINUTES POST-ADMINISTRATION	2.84	ng/mL
				14DEC2011/09:09:03	30 MINUTES POST-ADMINISTRATION	3.35	ng/mL
				14DEC2011/09:24:03	45 MINUTES POST-ADMINISTRATION	2.83	ng/mL
				14DEC2011/09:39:03	60 MINUTES POST-ADMINISTRATION	2.44	ng/mL
				14DEC2011/09:54:06	75 MINUTES POST-ADMINISTRATION	2.06	ng/mL
				14DEC2011/10:09:06	90 MINUTES POST-ADMINISTRATION	1.96	ng/mL
				14DEC2011/10:39:06	120 MINUTES POST-ADMINISTRATION	1.74	ng/mL
				14DEC2011/11:09:05	150 MINUTES POST-ADMINISTRATION	1.53	ng/mL
				14DEC2011/11:39:05	180 MINUTES POST-ADMINISTRATION	1.35	ng/mL
			NICOTINE ADJ	14DEC2011/08:39:04	0 MINUTES POST-ADMINISTRATION	0.000	ng/mL
				14DEC2011/08:42:04	3 MINUTES POST-ADMINISTRATION	0.080	ng/mL
				14DEC2011/08:44:07	5 MINUTES POST-ADMINISTRATION	0.583	ng/mL
				14DEC2011/08:46:35	7.5 MINUTES POST-ADMINISTRATION	0.929	ng/mL
				14DEC2011/08:49:03	10 MINUTES POST-ADMINISTRATION	1.035	ng/mL
				14DEC2011/08:54:04	15 MINUTES POST-ADMINISTRATION	1.365	ng/mL
				14DEC2011/08:59:05	20 MINUTES POST-ADMINISTRATION	1.815	ng/mL
				14DEC2011/09:09:03	30 MINUTES POST-ADMINISTRATION	2.383	ng/mL
				14DEC2011/09:24:03	45 MINUTES POST-ADMINISTRATION	1.943	ng/mL
				14DEC2011/09:39:03	60 MINUTES POST-ADMINISTRATION	1.627	ng/mL
				14DEC2011/09:54:06	75 MINUTES POST-ADMINISTRATION	1.314	ng/mL
				14DEC2011/10:09:06	90 MINUTES POST-ADMINISTRATION	1.276	ng/mL
				14DEC2011/10:39:06	120 MINUTES POST-ADMINISTRATION	1.165	ng/mL
				14DEC2011/11:09:05	150 MINUTES POST-ADMINISTRATION	1.046	ng/mL
				14DEC2011/11:39:05	180 MINUTES POST-ADMINISTRATION	0.943	ng/mL

Listing 16.2.5.1
Serum Concentrations

(b) (4)



Listing 16.2.5.1
Serum Concentrations

(b) (4)



Listing 16.2.5.2
Derived Nicotine Uptake Parameter Estimates

Subject	Product	Age/Sex/ Race	AUC ₀₋₁₈₀ [(ng x min)/mL]	AUC _{adj} [(ng x min)/mL]	C _{max} (ng/mL)	C _{max(adj)} (ng/mL)	T _{max(adj)} (min)	AUC _{ratio}	Elimination Rate (l/min) *
01	Subject-specific, UB Cigarette	43/F/Ca	1464.2	1186.3	21.90	19.53	7.5		0.0076
	(b) (4)								
02	Subject-specific, UB Cigarette	48/M/Ca	795.1	767.1	19.90	19.66	7.5		0.0061
	(b) (4)								
03	Subject-specific, UB Cigarette	36/F/Ca	1924.2	1246.3	16.20	10.65	15.0		0.0075
	(b) (4)								
04	Subject-specific, UB Cigarette	26/M/Ca	1045.9	978.4	37.70	37.12	5.0		0.0093
		26/M/Ca	638.9	538.5	7.16	6.41	30.0	55.0	0.0068
	(b) (4)								
05	Subject-specific, UB Cigarette	30/F/Ca	931.1	804.5	16.00	14.92	7.5		0.0039
	(b) (4)								

* In all cases the ratio of AUC_{0-∞} to AUC₀₋₁₈₀ > 1.25 (except for Subject 04 with Subject-specific, UB Cigarette), indicating that the elimination rates may be unreliable.

Listing 16.2.5.2
Derived Nicotine Uptake Parameter Estimates

Subject	Product	Age/Sex/ Race	AUC ₀₋₁₈₀ [(ng x min)/mL]	AUC _{adj} [(ng x min)/mL]	C _{max} (ng/mL)	C _{max(adj)} (ng/mL)	T _{max(adj)} (min)	AUC _{ratio}	Elimination Rate (1/min) *
06	Subject-specific, UB Cigarette	35/F/Ca	588.0	560.0	8.35	8.11	10.0		0.0074
(b) (4)									
07	Subject-specific, UB Cigarette	51/F/Ca	845.7	781.5	10.10	9.56	10.0		0.0067
08	Subject-specific, UB Cigarette	31/F/Ca	1094.6	964.6	9.94	8.88	15.0		0.0035
		31/F/Ca	254.4	197.7	1.86	1.43	30.0	20.5	0.0032
(b) (4)									
09	Subject-specific, UB Cigarette	47/F/Ca	917.3	788.5	12.10	11.00	7.5		0.0081
(b) (4)									
10	Subject-specific, UB Cigarette	41/F/Ca	769.6	675.8	7.54	6.79	20.0		0.0069
(b) (4)									
11	Subject-specific, UB Cigarette	32/F/Af	957.5	846.4	30.90	29.94	5.0		0.0060
		32/F/Af	257.2	160.0	2.14	1.37	20.0	18.9	0.0039
(b) (4)									

* In all cases the ratio of AUC_{0-∞} to AUC₀₋₁₈₀ > 1.25 (except for Subject 04 with Subject-specific, UB Cigarette), indicating that the elimination rates may be unreliable.

Listing 16.2.5.2
Derived Nicotine Uptake Parameter Estimates

Subject	Product	Age/Sex/ Race	AUC ₀₋₁₈₀ [(ng x min)/mL]	AUC _{adj} [(ng x min)/mL]	C _{max} (ng/mL)	C _{max(adj)} (ng/mL)	T _{max(adj)} (min)	AUC _{ratio}	Elimination Rate (l/min) *
12	Subject-specific, UB Cigarette	25/M/Ca	2584.8	2023.4	39.30	34.43	5.0		0.0024
(b) (4)									
13	Subject-specific, UB Cigarette	26/F/Ca	604.5	530.7	7.14	6.54	15.0		0.0071
(b) (4)									
14	Subject-specific, UB Cigarette	35/F/Ca	1202.9	1103.9	10.50	9.67	10.0		0.0056
(b) (4)									
15	Subject-specific, UB Cigarette	26/M/Ca	1356.8	1273.2	18.00	17.30	10.0		0.0046
(b) (4)									
16	Subject-specific, UB Cigarette	53/M/Ca	1177.2	1037.1	22.60	21.39	5.0		0.0062
		53/M/Ca	1088.0	893.1	10.60	9.26	45.0	86.1	0.0068
(b) (4)									

* In all cases the ratio of AUC_{0-∞} to AUC₀₋₁₈₀ > 1.25 (except for Subject 04 with Subject-specific, UB Cigarette), indicating that the elimination rates may be unreliable.

Listing 16.2.5.2
Derived Nicotine Uptake Parameter Estimates

Subject Product	Age/Sex/ Race	AUC ₀₋₁₈₀ [(ng x min)/mL]	AUC _{adj} [(ng x min)/mL]	C _{max} (ng/mL)	C _{max(adj)} (ng/mL)	T _{max(adj)} (min)	AUC _{ratio}	Elimination Rate (1/min) *
17	Subject-specific, UB Cigarette	29/M/Ca	974.4	801.9	15.70	14.25	10.0	0.0068
		29/M/Ca	369.3	240.4	3.35	2.38	30.0	0.0042
(b) (4)								

* In all cases the ratio of AUC_{0-∞} to AUC₀₋₁₈₀ > 1.25 (except for Subject 04 with Subject-specific, UB Cigarette), indicating that the elimination rates may be unreliable.

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020502.SAS EXECUTED: 19AUG2012 15:39

Listing 16.2.5.3
Product Administration

(b) (4)



Listing 16.2.5.3
Product Administration

(b) (4)



Listing 16.2.5.3
Product Administration

(b) (4)



Listing 16.2.5.4
Study Product Sampling

(b) (4)



Listing 16.2.5.4
Study Product Sampling

(b) (4)



Listing 16.2.5.4
Study Product Sampling

(b) (4)



16.2.6 Individual Questionnaire, Expired Carbon Monoxide, and Oral Health and Physical Examination Data

Listing Number	Listing Title
16.2.6.1	Mood and Physical Symptoms Scale
16.2.6.2	Fagerström Test
16.2.6.3	Expired Carbon Monoxide Results
16.2.6.4	Oral Health and Physical Examination

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
01		43/F/Ca	10OCT2011/ 13:00:00	Screening	1	1	1	1	2	1	3
	Subject-specific, UB Cigarette	43/F/Ca	31OCT2011/ 08:54:40	Visit 1/ pre-insert	1	1	1	2	1	4	4
			31OCT2011/ 09:19:19	Visit 1/ 5'	1	1	1	1	1	2	0
			31OCT2011/ 09:27:59	Visit 1/ 15'	1	1	1	1	1	2	0
			31OCT2011/ 09:42:58	Visit 1/ 30'	1	1	1	1	1	2	0
			31OCT2011/ 09:57:56	Visit 1/ 45'	1	1	1	1	1	2	2
			31OCT2011/ 10:12:59	Visit 1/ 60'	1	1	1	1	1	2	2
			31OCT2011/ 10:42:56	Visit 1/ 90'	1	1	1	1	1	2	2
			31OCT2011/ 11:12:53	Visit 1/ 120'	1	1	1	1	1	2	3
			31OCT2011/ 11:42:55	Visit 1/ 150'	1	1	1	1	4	4	4
			31OCT2011/ 12:12:54	Visit 1/ 180'	1	1	1	1	4	4	4

(b) (4)

{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely
{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020601.SAS EXECUTED: 19AUG2012 15:40

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Age/Sex/ Date/Time	Visit/	Depressed	Anxious	Irritable	Restless	Hungry	Poor	Concen-	Current	Urge
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(b) (4)



{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely

{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020601.SAS EXECUTED: 19AUG2012 15:40

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
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(b) (4)

Camel	SNUS	43/F/Ca	05DEC2011/ 08:37:53	Visit 5/ pre-insert	1	1	1	1	1	1	5
			05DEC2011/ 08:52:51	Visit 5/ 5'	1	1	1	1	1	2	5
			05DEC2011/ 09:03:00	Visit 5/ 15'	1	1	1	1	1	2	5

{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely
{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020601.SAS EXECUTED: 19AUG2012 15:40

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
01	Camel SNUS	43/F/Ca	05DEC2011/ 09:18:05	Visit 5/ 30'	1	1	1	1	3	3	4
			05DEC2011/ 09:32:55	Visit 5/ 45'	1	1	1	1	3	3	3
			05DEC2011/ 09:47:49	Visit 5/ 60'	1	1	1	1	2	3	3
			05DEC2011/ 10:18:22	Visit 5/ 90'	1	1	1	1	3	3	4
			05DEC2011/ 10:48:17	Visit 5/ 120'	1	1	1	1	2	2	3
			05DEC2011/ 11:18:10	Visit 5/ 150'	1	1	1	1	3	3	4
			05DEC2011/ 11:48:26	Visit 5/ 180'	1	1	1	1	4	4	5
02		48/M/Ca	11OCT2011/ 14:58:00	Screening	1	1	1	1	3	1	2
	Subject-specific, UB Cigarette	48/M/Ca	31OCT2011/ 08:30:28	Visit 1/ pre-insert	1	3	2	2	1	2	4
			31OCT2011/ 09:06:53	Visit 1/ 5'	1	1	1	1	1	1	0
			31OCT2011/ 09:16:24	Visit 1/ 15'	1	2	1	2	3	1	1
			31OCT2011/ 09:31:26	Visit 1/ 30'	1	2	1	2	2	1	2
			31OCT2011/ 09:46:14	Visit 1/ 45'	1	3	2	2	3	1	2
			31OCT2011/ 10:01:47	Visit 1/ 60'	2	2	2	3	3	1	3
			31OCT2011/ 10:31:31	Visit 1/ 90'	2	3	3	3	3	2	3

{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely

{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
02	Subject-specific, UB Cigarette	48/M/Ca	31OCT2011/ 11:01:44	Visit 1/ 120'	2	3	4	4	4	2	4
			31OCT2011/ 11:31:42	Visit 1/ 150'	1	3	3	4	3	2	4
			31OCT2011/	Visit 1/	1	4	3	3	4	2	4

(b) (4)

{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely
{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020601.SAS EXECUTED: 19AUG2012 15:40

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
02	(b) (4)										
	Camel SNUS	48/M/Ca	28NOV2011/ 08:43:05	Visit 4/ pre-insert	1	2	2	1	1	1	2
			28NOV2011/ 08:56:18	Visit 4/ 5'	1	1	1	1	1	1	1
			28NOV2011/ 09:06:39	Visit 4/ 15'	1	1	1	1	1	1	1
			28NOV2011/ 09:21:23	Visit 4/ 30'	2	2	2	1	1	1	2
			28NOV2011/ 09:36:20	Visit 4/ 45'	3	3	3	2	2	2	3
			28NOV2011/ 09:51:25	Visit 4/ 60'	2	3	3	3	2	2	2
			28NOV2011/ 10:21:35	Visit 4/ 90'	2	3	3	3	3	2	3

{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely
{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020601.SAS EXECUTED: 19AUG2012 15:40

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
02	Camel SNUS	48/M/Ca	28NOV2011/ 10:51:23	Visit 4/ 120'	2	3	3	4	3	1	4
			28NOV2011/ 11:21:52	Visit 4/ 150'	2	4	3	4	4	2	4
			28NOV2011/ 11:51:28	Visit 4/ 180'	2	4	3	4	4	2	4

(b) (4)

03		36/F/Ca	10OCT2011/ 12:46:00	Screening	1	1	1	1	1	1	1
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{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely

{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020601.SAS EXECUTED: 19AUG2012 15:40

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
03	Subject-specific, UB Cigarette	36/F/Ca	31OCT2011/ 08:24:15	Visit 1/ pre-insert	1	2	2	3	2	2	4
			31OCT2011/ 09:04:16	Visit 1/ 5'	1	1	1	2	1	1	1
			31OCT2011/ 09:14:12	Visit 1/ 15'	1	2	1	1	1	1	2
			31OCT2011/ 09:28:38	Visit 1/ 30'	1	1	1	2	1	1	2
			31OCT2011/ 09:43:32	Visit 1/ 45'	1	2	1	2	1	1	2
			31OCT2011/ 09:58:19	Visit 1/ 60'	1	1	1	2	2	1	3
			31OCT2011/ 10:28:29	Visit 1/ 90'	1	1	1	2	2	1	4
			31OCT2011/ 10:58:19	Visit 1/ 120'	1	2	1	3	1	1	4
			31OCT2011/ 11:28:19	Visit 1/ 150'	1	1	2	2	1	1	4
			31OCT2011/ 11:58:19	Visit 1/ 180'	1	2	2	2	1	1	5

(b) (4)

{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely
{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020601.SAS EXECUTED: 19AUG2012 15:40

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
03	(b) (4)										
	Camel SNUS	36/F/Ca	14NOV2011/ 08:41:15	Visit 3/ pre-insert	1	2	2	1	1	1	5
			14NOV2011/ 08:56:31	Visit 3/ 5'	1	2	1	1	1	1	4
			14NOV2011/ 09:06:22	Visit 3/ 15'	1	1	2	1	1	1	4
			14NOV2011/ 09:21:26	Visit 3/ 30'	1	1	2	2	1	1	4
			14NOV2011/ 09:36:27	Visit 3/ 45'	1	1	2	2	2	1	4
			14NOV2011/ 09:51:16	Visit 3/ 60'	1	1	2	2	2	1	4
			14NOV2011/ 10:21:27	Visit 3/ 90'	1	1	1	2	1	1	4
			14NOV2011/ 10:51:29	Visit 3/ 120'	1	1	2	2	1	1	4
			14NOV2011/ 11:21:48	Visit 3/ 150'	1	1	1	2	1	1	5
			14NOV2011/ 11:51:28	Visit 3/ 180'	1	1	2	3	1	1	4

{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely

{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020601.SAS EXECUTED: 19AUG2012 15:40

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/Date/Time Race Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
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(b) (4)



{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely

{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020601.SAS EXECUTED: 19AUG2012 15:40

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
03	(b) (4)										
04											
	Subject-specific, UB Cigarette	26/M/Ca	31OCT2011/ 08:45:52	Visit 1/ pre-insert	1	1	1	2	1	1	3
			31OCT2011/ 09:12:17	Visit 1/ 5'	1	1	1	1	1	1	0
			31OCT2011/ 09:22:30	Visit 1/ 15'	1	1	1	1	1	1	0
			31OCT2011/ 09:37:56	Visit 1/ 30'	1	1	1	1	1	1	0
			31OCT2011/ 09:52:25	Visit 1/ 45'	1	1	1	1	1	1	1
			31OCT2011/ 10:07:51	Visit 1/ 60'	1	1	1	1	2	1	2
			31OCT2011/ 10:37:14	Visit 1/ 90'	1	1	1	2	1	1	2
			31OCT2011/ 11:07:11	Visit 1/ 120'	1	1	1	2	1	1	2
			31OCT2011/ 11:37:21	Visit 1/ 150'	1	1	1	2	1	1	2

{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely

{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
04	Subject-specific, UB Cigarette	26/M/Ca	31OCT2011/ 12:07:15	Visit 1/ 180'	1	1	1	2	1	1	2
	Camel SNUS	26/M/Ca	07NOV2011/ 08:32:36	Visit 2/ pre-insert	1	1	1	1	1	1	3
			07NOV2011/ 08:52:55	Visit 2/ 5'	1	1	1	1	1	1	2
			07NOV2011/ 09:03:15	Visit 2/ 15'	1	1	1	1	1	1	2
			07NOV2011/ 09:18:35	Visit 2/ 30'	1	1	1	1	1	1	0
			07NOV2011/ 09:33:19	Visit 2/ 45'	1	1	1	2	1	1	0
			07NOV2011/ 09:48:07	Visit 2/ 60'	1	1	1	1	1	1	1
			07NOV2011/ 10:18:34	Visit 2/ 90'	1	1	1	2	1	1	1
			07NOV2011/ 10:48:03	Visit 2/ 120'	1	1	1	2	1	1	2
			07NOV2011/ 11:18:50	Visit 2/ 150'	1	1	1	2	1	1	2
			07NOV2011/ 11:48:31	Visit 2/ 180'	1	1	1	1	1	1	2

{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely

{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020601.SAS EXECUTED: 19AUG2012 15:40

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
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04 (b) (4)

{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely
{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020601.SAS EXECUTED: 19AUG2012 15:40

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
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04 (b) (4)

{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely
{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020601.SAS EXECUTED: 19AUG2012 15:40

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
04	(b) (4)										
05		30/F/Ca	14OCT2011/ 12:38:00	Screening	1	2	1	1	2	1	3
	Subject-specific, UB Cigarette	30/F/Ca	01NOV2011/ 08:37:58	Visit 1/ pre-insert	1	1	1	1	2	1	2
			01NOV2011/ 09:14:37	Visit 1/ 5'	1	1	1	1	2	1	0

{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely

{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020601.SAS EXECUTED: 19AUG2012 15:40

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
05	Subject-specific, UB Cigarette	30/F/Ca	01NOV2011/ 09:24:16	Visit 1/ 15'	1	1	1	1	2	1	1
			01NOV2011/ 09:39:12	Visit 1/ 30'	1	1	1	1	2	1	1
			01NOV2011/ 09:54:09	Visit 1/ 45'	1	1	1	1	2	1	1
			01NOV2011/ 10:09:11	Visit 1/ 60'	1	1	1	1	2	1	2
			01NOV2011/ 10:39:15	Visit 1/ 90'	1	1	1	1	2	1	2
			01NOV2011/ 11:09:01	Visit 1/ 120'	1	1	1	2	2	1	2
			01NOV2011/ 11:39:34	Visit 1/ 150'	1	1	1	2	2	1	2
			01NOV2011/ 12:09:07	Visit 1/ 180'	1	1	1	2	2	1	3

(b) (4)

{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely
{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020601.SAS EXECUTED: 19AUG2012 15:40

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
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05 (b) (4)

{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely
{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020601.SAS EXECUTED: 19AUG2012 15:40

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
05	(b) (4)										
	Camel SNUS	30/F/Ca	06DEC2011/ 08:29:10	Visit 5/ pre-insert	1	1	2	1	1	1	3
			06DEC2011/ 08:48:09	Visit 5/ 5'	1	1	2	1	1	1	3
			06DEC2011/ 08:57:48	Visit 5/ 15'	1	1	1	1	1	1	2
			06DEC2011/ 09:13:07	Visit 5/ 30'	1	1	1	1	1	1	2
			06DEC2011/ 09:28:01	Visit 5/ 45'	1	1	1	1	1	1	2
			06DEC2011/ 09:43:07	Visit 5/ 60'	1	1	1	1	1	1	2
			06DEC2011/ 10:13:36	Visit 5/ 90'	1	1	1	1	1	1	2

{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely
{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
05	Camel SNUS	30/F/Ca	06DEC2011/ 10:43:58	Visit 5/ 120'	1	1	1	1	1	1	2
			06DEC2011/ 11:15:45	Visit 5/ 150'	1	1	2	2	1	1	2
			06DEC2011/ 11:43:40	Visit 5/ 180'	1	1	2	2	1	1	3
06		35/F/Ca	11OCT2011/ 14:20:00	Screening	1	1	1	2	3	1	2
	Subject-specific, UB Cigarette	35/F/Ca	01NOV2011/ 08:15:28	Visit 1/ pre-insert	1	2	2	1	2	2	5
			01NOV2011/ 09:14:52	Visit 1/ 5'	1	1	1	1	2	1	2
			01NOV2011/ 09:25:14	Visit 1/ 15'	1	1	1	1	2	1	0
			01NOV2011/ 09:40:17	Visit 1/ 30'	1	1	1	1	2	1	1
			01NOV2011/ 09:55:15	Visit 1/ 45'	1	1	1	1	2	1	1
			01NOV2011/ 10:10:14	Visit 1/ 60'	1	1	1	1	3	1	1
			01NOV2011/ 10:40:20	Visit 1/ 90'	1	1	1	2	3	1	2
			01NOV2011/ 11:10:07	Visit 1/ 120'	1	1	1	1	3	1	3
			01NOV2011/ 11:40:12	Visit 1/ 150'	1	1	1	1	4	1	4
			01NOV2011/ 12:11:45	Visit 1/ 180'	1	1	1	2	4	1	4

{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely

{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
06	(b) (4)										
	Camel SNUS	35/F/Ca	15NOV2011/ 08:46:53	Visit 3/ pre-insert	1	1	1	1	2	1	4
			15NOV2011/ 09:04:10	Visit 3/ 5'	1	1	1	1	2	1	4
			15NOV2011/ 09:14:19	Visit 3/ 15'	1	1	1	1	2	1	3
			15NOV2011/ 09:29:11	Visit 3/ 30'	1	1	1	1	2	1	2
			15NOV2011/ 09:44:31	Visit 3/ 45'	1	1	1	1	1	1	2

{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely
{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020601.SAS EXECUTED: 19AUG2012 15:40

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
06	Camel SNUS	35/F/Ca	15NOV2011/ 09:59:32	Visit 3/ 60'	1	1	1	1	1	1	2
			15NOV2011/ 10:29:22	Visit 3/ 90'	1	1	1	1	1	1	2
			15NOV2011/ 10:59:35	Visit 3/ 120'	1	1	1	1	1	1	2
			15NOV2011/ 11:29:34	Visit 3/ 150'	1	1	1	1	2	1	3
			15NOV2011/ 11:59:40	Visit 3/ 180'	1	1	1	1	2	1	4

(b) (4)



{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely
{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020601.SAS EXECUTED: 19AUG2012 15:40

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
06	(b) (4)										
07		51/F/Ca	13OCT2011/ 12:27:00	Screening	1	1	1	1	2	1	1
	Subject-specific, UB Cigarette	51/F/Ca	01NOV2011/ 08:51:28	Visit 1/ pre-insert	1	2	2	2	2	2	4
			01NOV2011/ 09:16:15	Visit 1/ 5'	1	1	1	1	2	1	2
			01NOV2011/ 09:25:47	Visit 1/ 15'	1	1	1	1	2	1	1
			01NOV2011/ 09:41:06	Visit 1/ 30'	1	1	1	1	2	1	1

{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely

{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
07	Subject-specific, UB Cigarette	51/F/Ca	01NOV2011/ 09:56:06	Visit 1/ 45'	1	1	1	1	2	1	1
			01NOV2011/ 10:11:06	Visit 1/ 60'	1	1	1	1	2	1	1
			01NOV2011/ 10:41:09	Visit 1/ 90'	1	1	1	1	1	1	1
			01NOV2011/ 11:11:17	Visit 1/ 120'	1	1	1	1	1	1	2
			01NOV2011/ 11:41:01	Visit 1/ 150'	1	1	1	1	1	1	2
			01NOV2011/ 12:11:00	Visit 1/ 180'	1	1	1	1	1	1	3
	NONE	51/F/Ca	08NOV2011/ 08:53:12	Visit 2/ pre-insert	1	2	3	1	1	1	3

{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely
{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
08		31/F/Ca	12OCT2011/ 15:17:00	Screening	1	1	1	1	2	1	0
	Subject-specific, UB Cigarette	31/F/Ca	01NOV2011/ 09:06:29	Visit 1/ pre-insert	1	3	3	1	1	1	4
			01NOV2011/ 09:30:32	Visit 1/ 5'	1	1	1	1	1	1	1
			01NOV2011/ 09:40:02	Visit 1/ 15'	1	1	1	1	1	1	0
			01NOV2011/ 09:55:04	Visit 1/ 30'	1	1	1	1	1	1	1
			01NOV2011/ 10:09:43	Visit 1/ 45'	1	1	1	1	1	1	1
			01NOV2011/ 10:24:58	Visit 1/ 60'	1	1	1	1	1	1	1
			01NOV2011/ 10:55:09	Visit 1/ 90'	1	1	1	1	1	1	2
			01NOV2011/ 11:25:56	Visit 1/ 120'	1	1	2	1	1	1	2
			01NOV2011/ 11:55:08	Visit 1/ 150'	1	1	1	1	1	1	2
			01NOV2011/ 12:25:09	Visit 1/ 180'	1	1	1	1	1	1	2
	Camel SNUS	31/F/Ca	08NOV2011/ 08:44:58	Visit 2/ pre-insert	1	3	3	3	1	1	4
			08NOV2011/ 09:01:23	Visit 2/ 5'	1	2	2	1	1	1	2

{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely

{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
08	Camel SNUS	31/F/Ca	08NOV2011/ 09:11:13	Visit 2/ 15'	1	2	1	1	1	1	2
			08NOV2011/ 09:26:16	Visit 2/ 30'	1	1	1	1	1	1	2
			08NOV2011/ 09:41:09	Visit 2/ 45'	1	1	1	1	1	1	2
			08NOV2011/ 09:56:02	Visit 2/ 60'	1	1	2	1	1	1	2
			08NOV2011/ 10:26:12	Visit 2/ 90'	1	1	2	2	1	1	3
			08NOV2011/ 10:56:05	Visit 2/ 120'	1	2	2	2	1	1	4
			08NOV2011/ 11:26:12	Visit 2/ 150'	1	2	2	2	1	1	5
			08NOV2011/ 11:56:05	Visit 2/ 180'	1	2	1	2	1	1	5

(b) (4)

{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely
{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020601.SAS EXECUTED: 19AUG2012 15:40

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
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08 (b) (4)

{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely
{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020601.SAS EXECUTED: 19AUG2012 15:40

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
08	(b) (4)										
09		47/F/Ca	17OCT2011/ 12:40:00	Screening	1	1	2	1	2	1	1
	Subject-specific, UB Cigarette	47/F/Ca	02NOV2011/ 08:28:10	Visit 1/ pre-insert	1	2	1	2	2	1	4
			02NOV2011/ 09:20:05	Visit 1/ 5'	1	2	1	2	2	1	2
			02NOV2011/ 09:30:04	Visit 1/ 15'	1	2	1	2	2	1	2
			02NOV2011/ 09:45:03	Visit 1/ 30'	1	2	1	2	2	1	2
			02NOV2011/ 09:59:57	Visit 1/ 45'	1	2	1	2	3	1	2
			02NOV2011/ 10:14:56	Visit 1/ 60'	1	2	1	2	3	1	1

{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely

{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
09	Subject-specific, UB Cigarette	47/F/Ca	02NOV2011/ 10:44:55	Visit 1/ 90'	1	2	1	2	2	1	1
			02NOV2011/ 11:15:11	Visit 1/ 120'	1	2	1	2	2	1	2
			02NOV2011/ 11:45:10	Visit 1/ 150'	1	2	1	2	2	1	2
			02NOV2011/ 12:14:52	Visit 1/ 180'	1	2	1	3	3	1	2

(b) (4)



{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely

{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
09	(b) (4)										
	Camel SNUS	47/F/Ca	30NOV2011/ 08:43:46	Visit 4/ pre-insert	1	2	1	3	1	2	4
			30NOV2011/ 08:59:10	Visit 4/ 5'	1	2	1	2	1	2	4
			30NOV2011/ 09:09:12	Visit 4/ 15'	1	2	1	2	1	1	3
			30NOV2011/ 09:24:15	Visit 4/ 30'	1	2	1	2	1	1	3
			30NOV2011/ 09:39:08	Visit 4/ 45'	1	2	1	2	2	1	3
			30NOV2011/ 09:54:22	Visit 4/ 60'	1	2	1	2	1	1	3

{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely

{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020601.SAS EXECUTED: 19AUG2012 15:40

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
09	Camel SNUS	47/F/Ca	30NOV2011/ 10:24:20	Visit 4/ 90'	1	1	1	2	1	1	3
			30NOV2011/ 10:54:21	Visit 4/ 120'	1	2	1	2	1	1	3
			30NOV2011/ 11:24:23	Visit 4/ 150'	1	1	1	2	1	1	4
			30NOV2011/ 11:54:11	Visit 4/ 180'	1	1	1	2	2	1	4

(b) (4)

10		41/F/Ca	12OCT2011/ 12:35:00	Screening	1	3	3	3	3	3	2
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{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely
{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020601.SAS EXECUTED: 19AUG2012 15:40

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
10	Subject-specific, UB Cigarette	41/F/Ca	02NOV2011/ 08:26:20	Visit 1/ pre-insert	1	3	3	3	3	2	3
			02NOV2011/ 09:18:20	Visit 1/ 5'	1	1	2	2	1	2	3
			02NOV2011/ 09:27:53	Visit 1/ 15'	1	2	1	1	1	1	2
			02NOV2011/ 09:43:11	Visit 1/ 30'	2	3	2	2	2	1	2
			02NOV2011/ 09:58:06	Visit 1/ 45'	2	2	3	1	2	2	2
			02NOV2011/ 10:13:20	Visit 1/ 60'	2	2	2	2	2	1	2
			02NOV2011/ 10:43:03	Visit 1/ 90'	2	2	2	1	2	1	2
			02NOV2011/ 11:13:21	Visit 1/ 120'	1	2	2	2	3	1	3
			02NOV2011/ 11:43:08	Visit 1/ 150'	1	2	2	2	3	1	3
			02NOV2011/ 12:13:08	Visit 1/ 180'	1	3	1	2	3	1	3
	Camel SNUS	41/F/Ca	09NOV2011/ 08:52:38	Visit 2/ pre-insert	1	2	1	1	2	1	3
			09NOV2011/ 09:13:52	Visit 2/ 5'	1	2	2	1	1	1	2
			09NOV2011/ 09:24:00	Visit 2/ 15'	1	1	2	1	2	1	2
			09NOV2011/ 09:38:40	Visit 2/ 30'	1	1	1	1	2	1	1
			09NOV2011/ 09:53:42	Visit 2/ 45'	1	1	1	1	2	1	2

{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely

{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
10	Camel SNUS	41/F/Ca	09NOV2011/ 10:08:38	Visit 2/ 60'	1	1	1	1	2	1	2
			09NOV2011/ 10:38:47	Visit 2/ 90'	1	1	2	1	2	1	2
			09NOV2011/ 11:08:43	Visit 2/ 120'	1	1	1	1	3	1	3
			09NOV2011/ 11:38:38	Visit 2/ 150'	1	1	1	1	4	1	3
			09NOV2011/ 12:08:34	Visit 2/ 180'	1	1	2	2	4	1	4

(b) (4)



{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely

{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020601.SAS EXECUTED: 19AUG2012 15:40

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
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10 (b) (4)

{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely

{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020601.SAS EXECUTED: 19AUG2012 15:40

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
10	(b) (4)										
11		32/F/Af	17OCT2011/ 16:17:00	Screening	1	1	1	1	3	1	1
	Subject-specific, UB Cigarette	32/F/Af	02NOV2011/ 08:48:51	Visit 1/ pre-insert	1	1	1	1	5	1	2
			02NOV2011/ 09:19:52	Visit 1/ 5'	1	1	1	1	4	1	0
			02NOV2011/ 09:29:57	Visit 1/ 15'	1	1	1	1	2	1	0
			02NOV2011/ 09:44:51	Visit 1/ 30'	1	1	1	1	2	1	1
			02NOV2011/ 09:59:53	Visit 1/ 45'	1	1	1	1	2	1	1
			02NOV2011/ 10:14:50	Visit 1/ 60'	1	1	1	1	2	1	1
			02NOV2011/ 10:51:54	Visit 1/ 90'	1	1	1	1	2	1	1
			02NOV2011/ 11:15:17	Visit 1/ 120'	1	1	1	1	2	1	1
			02NOV2011/ 11:44:58	Visit 1/ 150'	1	1	1	1	3	1	2

{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely

{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
11	Subject-specific, UB Cigarette	32/F/Af	02NOV2011/ 12:14:51	Visit 1/ 180'	1	1	1	1	3	1	2

(b) (4)

{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely
{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020601.SAS EXECUTED: 19AUG2012 15:40

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
11	Camel SNUS	32/F/Af	30NOV2011/ 08:41:39	Visit 3/ UNSCHEDULED/ pre-insert	1	1	1	1	1	1	1
			30NOV2011/ 08:57:23	Visit 3/ UNSCHEDULED/ 5'	1	1	1	1	1	1	0
			30NOV2011/ 09:07:32	Visit 3/ UNSCHEDULED/ 15'	1	1	1	1	1	1	0
			30NOV2011/ 09:22:27	Visit 3/ UNSCHEDULED/ 30'	1	1	1	1	1	1	0
			30NOV2011/ 09:37:53	Visit 3/ UNSCHEDULED/ 45'	1	1	1	1	1	1	1
			30NOV2011/ 09:52:15	Visit 3/ UNSCHEDULED/ 60'	1	1	1	1	1	1	1

{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely

{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020601.SAS EXECUTED: 19AUG2012 15:40

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
11	Camel SNUS	32/F/Af	30NOV2011/ 10:22:37	Visit 3/ UNSCHEDULED/ 90'	1	1	1	1	1	1	1
			30NOV2011/ 10:52:38	Visit 3/ UNSCHEDULED/ 120'	1	1	1	1	2	1	1
			30NOV2011/ 11:22:56	Visit 3/ UNSCHEDULED/ 150'	1	1	1	1	1	1	1
			30NOV2011/ 11:52:27	Visit 3/ UNSCHEDULED/ 180'	1	1	1	1	1	1	1

(b) (4)



{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely
{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020601.SAS EXECUTED: 19AUG2012 15:40

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
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11 (b) (4)

12		25/M/Ca	18OCT2011/ 14:50:00	Screening	2	2	1	1	2	3	2
	Subject-specific, UB Cigarette	25/M/Ca	02NOV2011/ 08:19:51	Visit 1/ pre-insert	1	1	2	1	3	1	4
			02NOV2011/ 09:18:35	Visit 1/ 5'	1	2	1	1	4	1	0

{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely

{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020601.SAS EXECUTED: 19AUG2012 15:40

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
12	Subject-specific, UB Cigarette	25/M/Ca	02NOV2011/ 09:28:38	Visit 1/ 15'	1	2	1	1	4	1	0
			02NOV2011/ 09:43:07	Visit 1/ 30'	1	1	1	1	3	1	1
			02NOV2011/ 09:58:13	Visit 1/ 45'	1	1	1	1	3	1	2
			02NOV2011/ 10:13:04	Visit 1/ 60'	1	1	1	1	3	1	2
			02NOV2011/ 10:43:22	Visit 1/ 90'	1	1	1	2	3	1	2
			02NOV2011/ 11:14:25	Visit 1/ 120'	1	1	1	2	3	1	3
			02NOV2011/ 11:44:05	Visit 1/ 150'	1	1	1	3	3	1	3
			02NOV2011/ 12:13:37	Visit 1/ 180'	1	2	1	3	4	1	3

(b) (4)

{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely
{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020601.SAS EXECUTED: 19AUG2012 15:40

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
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12 (b) (4)

{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely
{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020601.SAS EXECUTED: 19AUG2012 15:40

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
12	(b) (4)										
	Camel SNUS	25/M/Ca	07DEC2011/ 08:39:02	Visit 5/ pre-insert	1	1	1	1	1	1	5
			07DEC2011/ 08:57:01	Visit 5/ 5'	1	1	1	1	1	1	3
			07DEC2011/ 09:06:57	Visit 5/ 15'	1	1	1	1	1	1	1
			07DEC2011/ 09:21:42	Visit 5/ 30'	1	1	1	1	1	1	2
			07DEC2011/ 09:36:45	Visit 5/ 45'	1	1	1	1	1	1	2
			07DEC2011/ 09:52:02	Visit 5/ 60'	1	1	1	1	1	1	2
			07DEC2011/ 10:22:07	Visit 5/ 90'	1	1	1	1	1	1	2

{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely
{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020601.SAS EXECUTED: 19AUG2012 15:40

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
12	Camel SNUS	25/M/Ca	07DEC2011/ 10:52:28	Visit 5/ 120'	1	1	1	1	1	1	3
			07DEC2011/ 11:22:01	Visit 5/ 150'	1	1	1	1	1	1	3
			07DEC2011/ 11:52:24	Visit 5/ 180'	1	1	1	1	1	1	3
13		26/F/Ca	14OCT2011/ 12:52:00	Screening	1	1	1	1	2	1	1
	Subject-specific, UB Cigarette	26/F/Ca	03NOV2011/ 08:13:10	Visit 1/ pre-insert	1	2	1	2	1	1	5
			03NOV2011/ 08:58:56	Visit 1/ 5'	1	1	1	1	1	1	0
			03NOV2011/ 09:08:44	Visit 1/ 15'	1	1	1	1	1	1	0
			03NOV2011/ 09:23:47	Visit 1/ 30'	1	1	1	1	1	1	0
			03NOV2011/ 09:38:50	Visit 1/ 45'	1	1	1	1	1	1	0
			03NOV2011/ 09:53:48	Visit 1/ 60'	1	1	1	1	2	1	1
			03NOV2011/ 10:23:48	Visit 1/ 90'	1	1	1	1	2	1	1
			03NOV2011/ 10:53:47	Visit 1/ 120'	1	1	1	1	1	1	2
			03NOV2011/ 11:23:42	Visit 1/ 150'	1	1	1	1	2	1	2
			03NOV2011/ 11:53:40	Visit 1/ 180'	1	1	1	1	2	1	2

{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely

{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
13	(b) (4)										
	Camel SNUS	26/F/Ca	17NOV2011/ 08:39:11	Visit 3/ pre-insert	1	2	1	1	1	1	2
			17NOV2011/ 08:58:39	Visit 3/ 5'	1	1	1	1	1	1	1
			17NOV2011/ 09:08:33	Visit 3/ 15'	1	1	1	1	1	1	0
			17NOV2011/ 09:23:25	Visit 3/ 30'	1	1	1	1	1	1	0
			17NOV2011/ 09:38:27	Visit 3/ 45'	1	1	1	1	2	1	0

{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely

{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020601.SAS EXECUTED: 19AUG2012 15:40

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
13	Camel SNUS	26/F/Ca	17NOV2011/ 09:53:32	Visit 3/ 60'	1	1	1	1	2	1	1
			17NOV2011/ 10:24:03	Visit 3/ 90'	1	1	1	1	1	1	1
			17NOV2011/ 10:53:46	Visit 3/ 120'	1	1	1	1	1	1	1
			17NOV2011/ 11:24:23	Visit 3/ 150'	1	1	1	1	1	1	2
			17NOV2011/ 11:53:42	Visit 3/ 180'	1	1	1	1	1	1	2

(b) (4)



{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely
{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020601.SAS EXECUTED: 19AUG2012 15:40

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
13	(b) (4)										
14		35/F/Ca	11OCT2011/ 15:38:00	Screening	1	1	1	2	2	1	1
	Subject-specific, UB Cigarette	35/F/Ca	03NOV2011/ 08:17:14	Visit 1/ pre-insert	1	2	2	1	3	1	2
			03NOV2011/ 08:58:23	Visit 1/ 5'	1	3	4	3	2	1	1
			03NOV2011/ 09:08:24	Visit 1/ 15'	1	2	2	1	2	1	0
			03NOV2011/ 09:23:44	Visit 1/ 30'	1	1	2	2	2	1	0

{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely

{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020601.SAS EXECUTED: 19AUG2012 15:40

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
14	Subject-specific, UB Cigarette	35/F/Ca	03NOV2011/ 09:38:29	Visit 1/ 45'	1	1	2	2	2	1	0
			03NOV2011/ 09:53:37	Visit 1/ 60'	1	1	2	1	2	1	1
			03NOV2011/ 10:23:35	Visit 1/ 90'	1	1	1	2	2	1	1
			03NOV2011/ 10:53:45	Visit 1/ 120'	1	3	2	2	3	1	2
			03NOV2011/ 11:23:31	Visit 1/ 150'	1	2	2	3	2	1	2
			03NOV2011/ 11:53:30	Visit 1/ 180'	1	2	2	2	2	1	3

(b) (4)

{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely
{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020601.SAS EXECUTED: 19AUG2012 15:40

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
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14 (b) (4)

Camel	SNUS	35/F/Ca	01DEC2011/ 08:52:09	Visit 4/ pre-insert	2	1	2	2	1	1	4
			01DEC2011/ 09:06:04	Visit 4/ 5'	2	2	2	2	1	1	3
			01DEC2011/ 09:16:20	Visit 4/ 15'	2	2	2	2	1	1	2
			01DEC2011/ 09:31:22	Visit 4/ 30'	2	2	2	1	1	1	2

{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely
{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020601.SAS EXECUTED: 19AUG2012 15:40

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
14	Camel SNUS	35/F/Ca	01DEC2011/ 09:46:15	Visit 4/ 45'	2	2	2	1	1	1	2
			01DEC2011/ 10:01:09	Visit 4/ 60'	2	2	2	2	1	1	2
			01DEC2011/ 10:31:06	Visit 4/ 90'	2	2	2	2	1	1	2
			01DEC2011/ 11:01:29	Visit 4/ 120'	2	2	2	1	3	2	2
			01DEC2011/ 11:31:14	Visit 4/ 150'	2	2	2	2	2	1	3
			01DEC2011/ 12:01:04	Visit 4/ 180'	2	2	2	2	1	1	2

(b) (4)



{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely
{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020601.SAS EXECUTED: 19AUG2012 15:40

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
14	(b) (4)										
15		26/M/Ca	14OCT2011/ 13:37:00	Screening	1	2	1	2	3	1	2
	Subject-specific, UB Cigarette	26/M/Ca	03NOV2011/ 08:07:15	Visit 1/ pre-insert	2	2	4	2	1	3	5
			03NOV2011/ 09:02:15	Visit 1/ 5'	1	1	1	2	1	1	0
			03NOV2011/ 09:12:04	Visit 1/ 15'	1	2	1	2	1	1	0
			03NOV2011/ 09:27:08	Visit 1/ 30'	1	2	1	2	1	1	1
			03NOV2011/ 09:41:59	Visit 1/ 45'	1	1	1	2	1	1	1
			03NOV2011/ 09:57:17	Visit 1/ 60'	1	1	1	2	1	1	2
			03NOV2011/ 10:27:15	Visit 1/ 90'	1	1	1	2	1	1	3
			03NOV2011/ 10:56:58	Visit 1/ 120'	1	1	1	2	1	1	3
			03NOV2011/ 11:26:47	Visit 1/ 150'	1	2	2	3	2	1	4
			03NOV2011/ 11:56:52	Visit 1/ 180'	1	3	3	4	2	2	4
	Camel SNUS	26/M/Ca	10NOV2011/ 08:32:38	Visit 2/ pre-insert	1	1	2	1	1	2	3
			10NOV2011/ 08:52:53	Visit 2/ 5'	1	1	1	1	1	1	1

{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely

{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
15	Camel SNUS	26/M/Ca	10NOV2011/ 09:03:02	Visit 2/ 15'	1	1	1	1	1	1	1
			10NOV2011/ 09:18:09	Visit 2/ 30'	1	1	1	1	1	1	1
			10NOV2011/ 09:33:13	Visit 2/ 45'	1	1	1	2	1	1	1
			10NOV2011/ 09:48:12	Visit 2/ 60'	1	1	1	2	1	1	1
			10NOV2011/ 10:18:52	Visit 2/ 90'	1	1	1	2	1	1	2
			10NOV2011/ 10:48:20	Visit 2/ 120'	1	1	1	2	2	1	2
			10NOV2011/ 11:18:33	Visit 2/ 150'	1	1	1	2	1	1	3
			10NOV2011/ 11:48:19	Visit 2/ 180'	1	1	1	2	2	1	3

(b) (4)

{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely
{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020601.SAS EXECUTED: 19AUG2012 15:40

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
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15 (b) (4)

{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely
{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020601.SAS EXECUTED: 19AUG2012 15:40

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
15	(b) (4)										
16		53/M/Ca	13OCT2011/ 12:26:00	Screening	1	1	1	1	3	1	1
	Subject-specific, UB Cigarette	53/M/Ca	03NOV2011/ 08:02:58	Visit 1/ pre-insert	1	2	1	1	2	1	2
			03NOV2011/ 09:01:12	Visit 1/ 5'	1	1	1	1	2	1	0
			03NOV2011/ 09:11:00	Visit 1/ 15'	1	1	1	1	2	1	0
			03NOV2011/ 09:26:09	Visit 1/ 30'	1	1	1	1	1	1	0
			03NOV2011/ 09:40:55	Visit 1/ 45'	1	1	1	1	1	1	1
			03NOV2011/ 09:55:57	Visit 1/ 60'	1	1	1	1	1	1	1

{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely

{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020601.SAS EXECUTED: 19AUG2012 15:40

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
16	Subject-specific, UB Cigarette	53/M/Ca	03NOV2011/ 10:26:00	Visit 1/ 90'	1	1	1	1	1	1	1
			03NOV2011/ 10:56:04	Visit 1/ 120'	1	1	1	1	1	1	1
			03NOV2011/ 11:25:57	Visit 1/ 150'	1	1	1	1	1	1	1
			03NOV2011/ 11:55:54	Visit 1/ 180'	1	1	1	1	1	1	2

(b) (4)

{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely
{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020601.SAS EXECUTED: 19AUG2012 15:40

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
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16 (b) (4)

{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely
{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020601.SAS EXECUTED: 19AUG2012 15:40

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
16	(b) (4)										
	Camel SNUS	53/M/Ca	08DEC2011/ 08:31:10	Visit 5/ pre-insert	1	1	1	1	2	1	2
			08DEC2011/ 08:48:31	Visit 5/ 5'	1	1	1	1	2	1	2
			08DEC2011/ 08:58:41	Visit 5/ 15'	1	1	1	1	2	1	2
			08DEC2011/ 09:13:56	Visit 5/ 30'	1	1	1	1	2	1	2
			08DEC2011/ 09:28:24	Visit 5/ 45'	1	1	1	1	1	1	2
			08DEC2011/ 09:43:44	Visit 5/ 60'	1	1	1	1	1	1	2
			08DEC2011/ 10:13:48	Visit 5/ 90'	1	1	1	1	1	1	2
			08DEC2011/ 10:43:47	Visit 5/ 120'	1	1	1	1	1	1	2
			08DEC2011/ 11:14:29	Visit 5/ 150'	1	1	1	1	1	1	2
			08DEC2011/ 11:45:00	Visit 5/ 180'	1	1	1	1	1	1	2
17		29/M/Ca	18OCT2011/ 12:38:00	Screening	1	2	1	1	1	1	3

{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely

{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020601.SAS EXECUTED: 19AUG2012 15:40

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
17	Subject-specific, UB Cigarette	29/M/Ca	01NOV2011/ 08:15:00	Visit 1/ pre-insert	1	1	1	1	2	1	4
	Subject-specific, UB Cigarette	29/M/Ca	15NOV2011/ 08:50:02	Visit 1/ UNSCHEDULED/ pre-insert	1	1	1	1	2	1	3
			15NOV2011/ 09:59:02	Visit 1/ UNSCHEDULED/ 5'	1	1	1	1	2	1	0
			15NOV2011/ 10:09:03	Visit 1/ UNSCHEDULED/ 15'	1	1	1	1	2	1	0

{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely
{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020601.SAS EXECUTED: 19AUG2012 15:40

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
17	Subject-specific, UB Cigarette	29/M/Ca	15NOV2011/ 10:23:56	Visit 1/ UNSCHEDULED/ 30'	1	1	1	1	1	1	1
			15NOV2011/ 10:38:58	Visit 1/ UNSCHEDULED/ 45'	1	1	1	1	1	1	1
			15NOV2011/ 10:53:54	Visit 1/ UNSCHEDULED/ 60'	1	1	1	1	1	1	2
			15NOV2011/ 11:24:10	Visit 1/ UNSCHEDULED/ 90'	1	1	1	1	1	1	2
			15NOV2011/ 11:53:59	Visit 1/ UNSCHEDULED/ 120'	1	1	1	1	1	1	3
			15NOV2011/ 12:24:16	Visit 1/ UNSCHEDULED/ 150'	1	1	1	1	1	1	2
			15NOV2011/ 12:53:56	Visit 1/ UNSCHEDULED/ 180'	1	1	1	1	1	1	2

(b) (4)

{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely
{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020601.SAS EXECUTED: 19AUG2012 15:40

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
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17 (b) (4)

{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely
{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020601.SAS EXECUTED: 19AUG2012 15:40

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/ Race	Date/Time Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
17	Camel SNUS	29/M/Ca	14DEC2011/ 08:21:29	Visit 4/ pre-insert	1	1	1	1	2	1	4
			14DEC2011/ 08:45:00	Visit 4/ 5'	1	1	1	1	2	1	4
			14DEC2011/ 08:54:42	Visit 4/ 15'	1	1	1	1	2	1	3
			14DEC2011/ 09:10:00	Visit 4/ 30'	1	1	1	1	2	1	3
			14DEC2011/ 09:24:51	Visit 4/ 45'	1	1	1	1	2	1	2
			14DEC2011/ 09:39:45	Visit 4/ 60'	1	1	1	1	1	1	3
			14DEC2011/ 10:09:32	Visit 4/ 90'	1	1	1	1	1	1	2
			14DEC2011/ 10:40:06	Visit 4/ 120'	1	1	1	1	1	1	2
			14DEC2011/ 11:10:09	Visit 4/ 150'	1	1	1	1	1	1	2
			14DEC2011/ 11:39:47	Visit 4/ 180'	1	1	1	1	1	1	3


(b) (4)

{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely
{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

Listing 16.2.6.1
Mood and Physical Symptoms Scale

Subject	Product	Age/Sex/Date/Time Race Obtained	Visit/ Time Point	Depressed {1}	Anxious {1}	Irritable {1}	Restless {1}	Hungry {1}	Poor Concen- tration {1}	Current Urge to Smoke {2}
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17 (b) (4)



{1} 1=Not at All, 2=Slightly, 3=Somewhat, 4=Very, 5=Extremely

{2} 0=No Urges, 1=Slight, 2=Moderate, 3=Strong, 4=Very Strong, 5=Extremely Strong

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020601.SAS EXECUTED: 19AUG2012 15:40

Listing 16.2.6.2
Fagerström Test

- {1} 1: Camel Snus, (b) (4)
- {2} How soon after you wake up do you smoke your first cigarette: (0) after 60 minutes (1) 31 - 50 minutes (2) 6-30 minutes (3) within 5 minutes
- {3} Do you find it difficult to refrain from smoking places where it is forbidden, for example, in church, at the library, in theaters? (0) No (1) Yes
- {4} Which cigarette would you hate to give up most? (1) The first one in the morning (0) Any other.
- {5} How many cigarettes per day do you smoke? (0) <=10 (1) 11-20 (2) 21-30 (3) >=31
- {6} Do you smoke more frequently during the first hours after waking than during the rest of the day? (0) No (1) Yes
- {7} Do you smoke if you are so ill that you are in bed most of the day? (0) No (1) Yes

Note: Refer to page 1 of Listing 16.2.6.2 for footnotes.

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020602.SAS EXECUTED: 09OCT2012 16:22

Listing 16.2.6.2
Fagerström Test

Subject	Product Sequence{1}	Age/Sex/ Race	Questionnaire Date	Q1 {2}	Q2 {3}	Q3 {4}	Q4 {5}	Q5 {6}	Q6 {7}	Total Score
01	3-2-4-1	43/F/Ca	10OCT2011	2	(b) (4)					
02	4-3-1-2	48/M/Ca	11OCT2011	1						
03	2-1-3-4	36/F/Ca	10OCT2011	2						
04	1-4-2-3	26/M/Ca	13OCT2011	2						
05	3-2-4-1	30/F/Ca	14OCT2011	2						
06	2-1-3-4	35/F/Ca	11OCT2011	2						
07	4-3-1-2	51/F/Ca	13OCT2011	2						
08	1-4-2-3	31/F/Ca	12OCT2011	2						
09	4-3-1-2	47/F/Ca	17OCT2011	3						
10	1-4-2-3	41/F/Ca	12OCT2011	1						
11	2-1-3-4	32/F/Af	17OCT2011	0						
12	3-2-4-1	25/M/Ca	18OCT2011	3						

Note: Refer to page 1 for footnotes.

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020602.SAS EXECUTED: 09OCT2012 16:22

Listing 16.2.6.2
Fagerström Test

Subject	Product Sequence{1}	Age/Sex/ Race	Questionnaire Date	Q1 {2}	Q2 {3}	Q3 {4}	Q4 {5}	Q5 {6}	Q6 {7}	Total Score
13	2-1-3-4	26/F/Ca	14OCT2011	(b) (4)						
14	4-3-1-2	35/F/Ca	11OCT2011							
15	1-4-2-3	26/M/Ca	14OCT2011							
16	3-2-4-1	53/M/Ca	13OCT2011							
17	4-3-1-2	29/M/Ca	18OCT2011							

Note: Refer to page 1 for footnotes.

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020602.SAS EXECUTED: 09OCT2012 16:22

Listing 16.2.6.3
Expired Carbon Monoxide Results

Subject	Product Sequence{1}	Age/Sex/ Race	Visit	Date/Time Obtained	ECO (ppm)	Comments
01	3-2-4-1	43/F/Ca	Screening	10OCT2011/12:45	19	
			Visit 1	31OCT2011/08:31	6	
			Visit 2	07NOV2011/08:32	4	
			Visit 3	14NOV2011/08:31	7	
			Visit 4	28NOV2011/08:25	2	
			Visit 5	05DEC2011/08:32	5	
02	4-3-1-2	48/M/Ca	Screening	11OCT2011/14:25	24	
			Visit 1	31OCT2011/08:07	10	
			Visit 2	07NOV2011/08:32	8	
			Visit 3	14NOV2011/08:32	9	
			Visit 4	28NOV2011/08:36	10	
			Visit 5	05DEC2011/08:39	12	
03	2-1-3-4	36/F/Ca	Screening	10OCT2011/12:19	32	
			Visit 1	31OCT2011/08:09	10	
			Visit 2	07NOV2011/08:34	9	
			Visit 3	14NOV2011/08:35	7	
			Visit 4	28NOV2011/08:31	9	
			Visit 5	05DEC2011/08:30	7	
04	1-4-2-3	26/M/Ca	Screening	13OCT2011/13:12	22	
			Visit 1	31OCT2011/08:33	5	
			Visit 2	07NOV2011/08:29	6	
			Visit 3	16NOV2011/09:03	12	
			Visit	28NOV2011/08:26	12	
			3/UNSCHEDULED			
			Visit 4	05DEC2011/08:28	5	
			Visit 5	14DEC2011/08:32	8	

{1} 1: Camel SNUS, 2: STM-1, 3: STM-2, 4: STM-3

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020603.SAS EXECUTED: 09OCT2012 16:17

Listing 16.2.6.3
Expired Carbon Monoxide Results

Subject	Product Sequence{1}	Age/Sex/ Race	Visit	Date/Time Obtained	ECO (ppm)	Comments
05	3-2-4-1	30/F/Ca	Screening	14OCT2011/12:15	37	
			Visit 1	01NOV2011/08:33	3	
			Visit 2	08NOV2011/08:38	4	
			Visit 3	15NOV2011/08:33	2	
			Visit 4	29NOV2011/08:24	6	
			Visit 5	06DEC2011/08:28	3	
06	2-1-3-4	35/F/Ca	Screening	11OCT2011/15:18	31	
			Visit 1	01NOV2011/08:04	9	
			Visit 2	08NOV2011/08:36	12	
			Visit 3	15NOV2011/08:47	12	
			Visit 4	29NOV2011/08:36	10	
			Visit 5	06DEC2011/08:44	11	
07	4-3-1-2	51/F/Ca	Screening	13OCT2011/12:15	38	
			Visit 1	01NOV2011/08:33	12	
			Visit 2	08NOV2011/08:52	20	
			Visit	15NOV2011/08:29	21	
			2/UNSCHEDULED			
08	1-4-2-3	31/F/Ca	Screening	12OCT2011/14:49	42	
			Visit 1	01NOV2011/08:27	11	
			Visit 2	08NOV2011/08:42	10	
			Visit 3	15NOV2011/08:32	6	
			Visit 4	29NOV2011/08:30	12	
			Visit 5	06DEC2011/08:32	12	
09	4-3-1-2	47/F/Ca	Screening	17OCT2011/12:12	59	
			Visit 1	02NOV2011/08:09	12	
			Visit 2	09NOV2011/08:30	11	

{1} 1: Camel SNUS, 2: STM-1, 3: STM-2, 4: STM-3

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020603.SAS EXECUTED: 09OCT2012 16:17

Listing 16.2.6.3
Expired Carbon Monoxide Results

Subject	Product Sequence{1}	Age/Sex/ Race	Visit	Date/Time Obtained	ECO (ppm)	Comments
09	4-3-1-2	47/F/Ca	Visit 3	16NOV2011/08:29	10	
			Visit 4	30NOV2011/08:37	10	
			Visit 5	07DEC2011/08:34	8	
10	1-4-2-3	41/F/Ca	Screening	12OCT2011/12:28	25	
			Visit 1	02NOV2011/08:33	4	
			Visit 2	09NOV2011/08:47	7	
			Visit 3	16NOV2011/08:31	8	
			Visit 4	30NOV2011/08:28	8	
			Visit 5	07DEC2011/08:43	6	
11	2-1-3-4	32/F/Af	Screening	17OCT2011/15:44	16	
			Visit 1	02NOV2011/08:45	8	
			Visit 2	09NOV2011/08:30	5	
			Visit 3	17NOV2011/09:35	9	
			Visit	30NOV2011/08:36	9	
			3/UNSCHEDULED			
			Visit 4	07DEC2011/08:35	6	
12	3-2-4-1	25/M/Ca	Screening	18OCT2011/14:38	26	
			Visit 1	02NOV2011/08:17	11	
			Visit 2	09NOV2011/08:39	12	
			Visit 3	16NOV2011/08:38	12	
			Visit 4	30NOV2011/08:35	10	
			Visit 5	07DEC2011/08:33	10	
13	2-1-3-4	26/F/Ca	Screening	14OCT2011/12:31	37	
			Visit 1	03NOV2011/08:08	5	
			Visit 2	10NOV2011/08:31	4	

{1} 1: Camel SNUS, 2: STM-1, 3: STM-2, 4: STM-3

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020603.SAS EXECUTED: 09OCT2012 16:17

Listing 16.2.6.3
Expired Carbon Monoxide Results

Subject	Product Sequence{1}	Age/Sex/ Race	Visit	Date/Time Obtained	ECO (ppm)	Comments
13	2-1-3-4	26/F/Ca	Visit 3	17NOV2011/08:36	3	
			Visit 4	01DEC2011/08:30	2	
			Visit 5	08DEC2011/08:39	5	
14	4-3-1-2	35/F/Ca	Screening	11OCT2011/14:24	53	
			Visit 1	03NOV2011/08:10	11	
			Visit 2	10NOV2011/08:30	8	
			Visit 3	17NOV2011/08:31	9	
			Visit 4	01DEC2011/08:44	6	
			Visit 5	08DEC2011/08:47	5	
15	1-4-2-3	26/M/Ca	Screening	14OCT2011/13:30	24	
			Visit 1	03NOV2011/08:06	4	
			Visit 2	10NOV2011/08:30	5	
			Visit 3	17NOV2011/08:32	5	
			Visit 4	01DEC2011/08:34	6	
			Visit 5	08DEC2011/08:29	6	
16	3-2-4-1	53/M/Ca	Screening	13OCT2011/12:17	22	
			Visit 1	03NOV2011/07:34	12	
			Visit 2	10NOV2011/08:27	10	
			Visit 3	17NOV2011/08:29	11	
			Visit 4	01DEC2011/08:42	11	
			Visit 5	08DEC2011/08:29	11	
17	4-3-1-2	29/M/Ca	Screening	18OCT2011/12:18	37	
			Visit 1	01NOV2011/08:01	7	
			Visit 1/UNSCHEDULED	15NOV2011/08:40	12	
			Visit 2	29NOV2011/08:46	8	

{1} 1: Camel SNUS, 2: STM-1, 3: STM-2, 4: STM-3

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020603.SAS EXECUTED: 09OCT2012 16:17

Listing 16.2.6.3
Expired Carbon Monoxide Results

Subject	Product Sequence{1}	Age/Sex/ Race	Visit	Date/Time Obtained	ECO (ppm)	Comments
17	4-3-1-2	29/M/Ca	Visit 3	06DEC2011/08:39	10	
			Visit 4	14DEC2011/08:20	11	
			Visit 5	22DEC2011/08:16	7	

{1} 1: Camel SNUS, 2: STM-1, 3: STM-2, 4: STM-3

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020603.SAS EXECUTED: 09OCT2012 16:17

Listing 16.2.6.4
Oral Health and Physical Examination

Subject	Age/Sex/ Race	Visit	Date Obtained	Exam Item	Result
01	43/F/Ca	Screening	10OCT2011	Heart	NL
				Lungs	NL
				Abdomen	NL
				Skin	NL
				Ears/Nose/Throat (ENT)	NL
				Neck	NL
				Evidence of leukoplakia	NO
				Evidence of other oral keratosis	NO
				Evidence of oral lesions	NO
		Discharge Visit	05DEC2011	Heart	NL
				Lungs	NL
				Abdomen	NL
				Skin	NL
				Ears/Nose/Throat (ENT)	NL
				Neck	NL
				Evidence of leukoplakia	NO
				Evidence of other oral keratosis	NO
				Evidence of oral lesions	NO
02	48/M/Ca	Screening	11OCT2011	Heart	NL
				Lungs	NL
				Abdomen	NL
				Skin	NL
				Ears/Nose/Throat (ENT)	NL
				Neck	NL
				Evidence of leukoplakia	NO
				Evidence of other oral keratosis	NO
				Evidence of oral lesions	NO
		Discharge Visit	05DEC2011	Heart	NL
				Lungs	NL
				Abdomen	NL
				Skin	NL

Listing 16.2.6.4
Oral Health and Physical Examination

Subject	Age/Sex/ Race	Visit	Date Obtained	Exam Item	Result
02	48/M/Ca	Discharge Visit	05DEC2011	Ears/Nose/Throat (ENT)	NL
				Neck	NL
				Evidence of leukoplakia	NO
				Evidence of other oral keratosis	NO
				Evidence of oral lesions	NO
03	36/F/Ca	Screening	10OCT2011	Heart	NL
				Lungs	NL
				Abdomen	NL
				Skin	NL
				Ears/Nose/Throat (ENT)	NL
				Neck	NL
				Evidence of leukoplakia	NO
				Evidence of other oral keratosis	NO
				Evidence of oral lesions	NO
		Discharge Visit	05DEC2011	Heart	NL
				Lungs	NL
				Abdomen	NL
				Skin	NL
				Ears/Nose/Throat (ENT)	NL
				Neck	NL
				Evidence of leukoplakia	NO
				Evidence of other oral keratosis	NO
				Evidence of oral lesions	NO
04	26/M/Ca	Screening	13OCT2011	Heart	NL
				Lungs	NL
				Abdomen	NL
				Skin	NL
				Ears/Nose/Throat (ENT)	NL
				Neck	NL
				Evidence of leukoplakia	NO
				Evidence of other oral keratosis	NO
				Evidence of oral lesions	NO

Listing 16.2.6.4
Oral Health and Physical Examination

Subject	Age/Sex/ Race	Visit	Date Obtained	Exam Item	Result
04	26/M/Ca	Discharge Visit	14DEC2011	Heart	NL
				Lungs	NL
				Abdomen	NL
				Skin	NL
				Ears/Nose/Throat (ENT)	NL
				Neck	NL
				Evidence of leukoplakia	NO
				Evidence of other oral keratosis	NO
				Evidence of oral lesions	NO
05	30/F/Ca	Screening	14OCT2011	Heart	NL
				Lungs	NL
				Abdomen	NL
				Skin	NL
				Ears/Nose/Throat (ENT)	NL
				Neck	NL
				Evidence of leukoplakia	NO
				Evidence of other oral keratosis	NO
				Evidence of oral lesions	NO
		Discharge Visit	06DEC2011	Heart	NL
				Lungs	NL
				Abdomen	NL
				Skin	NL
				Ears/Nose/Throat (ENT)	ABN - NCS
				Neck	NL
				Evidence of leukoplakia	NO
				Evidence of other oral keratosis	NO
				Evidence of oral lesions	NO
06	35/F/Ca	Screening	11OCT2011	Heart	NL
				Lungs	NL
				Abdomen	NL
				Skin	NL
				Ears/Nose/Throat (ENT)	NL

Listing 16.2.6.4
Oral Health and Physical Examination

Subject	Age/Sex/ Race	Visit	Date Obtained	Exam Item	Result
06	35/F/Ca	Screening	11OCT2011	Neck	NL
				Evidence of leukoplakia	NO
				Evidence of other oral keratosis	NO
				Evidence of oral lesions	NO
		Discharge Visit	06DEC2011	Heart	NL
				Lungs	NL
				Abdomen	NL
				Skin	NL
				Ears/Nose/Throat (ENT)	NL
				Neck	NL
				Evidence of leukoplakia	NO
				Evidence of other oral keratosis	NO
				Evidence of oral lesions	NO
07	51/F/Ca	Screening	13OCT2011	Heart	NL
				Lungs	NL
				Abdomen	NL
				Skin	NL
				Ears/Nose/Throat (ENT)	NL
				Neck	NL
				Evidence of leukoplakia	NO
				Evidence of other oral keratosis	NO
				Evidence of oral lesions	NO
		Discharge Visit	15NOV2011	Heart	NL
				Lungs	NL
				Abdomen	NL
				Skin	NL
				Ears/Nose/Throat (ENT)	NL
				Neck	NL
				Evidence of leukoplakia	NO
				Evidence of other oral keratosis	NO
				Evidence of oral lesions	NO

Listing 16.2.6.4
Oral Health and Physical Examination

Subject	Age/Sex/ Race	Visit	Date Obtained	Exam Item	Result
08	31/F/Ca	Screening	12OCT2011	Heart	NL
				Lungs	NL
				Abdomen	NL
				Skin	NL
				Ears/Nose/Throat (ENT)	NL
				Neck	NL
				Evidence of leukoplakia	NO
				Evidence of other oral keratosis	NO
				Evidence of oral lesions	NO
		Discharge Visit	06DEC2011	Heart	NL
				Lungs	NL
				Abdomen	NL
				Skin	NL
				Ears/Nose/Throat (ENT)	NL
				Neck	NL
				Evidence of leukoplakia	NO
				Evidence of other oral keratosis	NO
				Evidence of oral lesions	NO
09	47/F/Ca	Screening	17OCT2011	Heart	NL
				Lungs	NL
				Abdomen	NL
				Skin	NL
				Ears/Nose/Throat (ENT)	NL
				Neck	NL
				Evidence of leukoplakia	NO
				Evidence of other oral keratosis	NO
				Evidence of oral lesions	NO
		Discharge Visit	07DEC2011	Heart	NL
				Lungs	NL
				Abdomen	NL
				Skin	NL
				Ears/Nose/Throat (ENT)	NL

Listing 16.2.6.4
Oral Health and Physical Examination

Subject	Age/Sex/ Race	Visit	Date Obtained	Exam Item	Result
09	47/F/Ca	Discharge Visit	07DEC2011	Neck Evidence of leukoplakia Evidence of other oral keratosis Evidence of oral lesions	NL NO NO NO
10	41/F/Ca	Screening	12OCT2011	Heart Lungs Abdomen Skin Ears/Nose/Throat (ENT) Neck Evidence of leukoplakia Evidence of other oral keratosis Evidence of oral lesions	NL NL NL NL NL NL NO NO NO
		Discharge Visit	07DEC2011	Heart Lungs Abdomen Skin Ears/Nose/Throat (ENT) Neck Evidence of leukoplakia Evidence of other oral keratosis Evidence of oral lesions	NL NL NL NL NL NL NO NO NO
11	32/F/Af	Screening	17OCT2011	Heart Lungs Abdomen Skin Ears/Nose/Throat (ENT) Neck Evidence of leukoplakia Evidence of other oral keratosis Evidence of oral lesions	NL NL NL NL NL NL NO NO NO

Listing 16.2.6.4
Oral Health and Physical Examination

Subject	Age/Sex/ Race	Visit	Date Obtained	Exam Item	Result
11	32/F/Af	Discharge Visit	14DEC2011	Heart	NL
				Lungs	NL
				Abdomen	NL
				Skin	NL
				Ears/Nose/Throat (ENT)	NL
				Neck	NL
				Evidence of leukoplakia	NO
				Evidence of other oral keratosis	NO
				Evidence of oral lesions	NO
12	25/M/Ca	Screening	18OCT2011	Heart	NL
				Lungs	NL
				Abdomen	NL
				Skin	NL
				Ears/Nose/Throat (ENT)	NL
				Neck	NL
				Evidence of leukoplakia	NO
				Evidence of other oral keratosis	NO
				Evidence of oral lesions	NO
		Discharge Visit	07DEC2011	Heart	NL
				Lungs	NL
				Abdomen	NL
				Skin	NL
				Ears/Nose/Throat (ENT)	NL
				Neck	NL
				Evidence of leukoplakia	NO
				Evidence of other oral keratosis	NO
				Evidence of oral lesions	NO
13	26/F/Ca	Screening	14OCT2011	Heart	NL
				Lungs	NL
				Abdomen	NL
				Skin	NL
				Ears/Nose/Throat (ENT)	NL

Listing 16.2.6.4
Oral Health and Physical Examination

Subject	Age/Sex/ Race	Visit	Date Obtained	Exam Item	Result
13	26/F/Ca	Screening	14OCT2011	Neck	NL
				Evidence of leukoplakia	NO
				Evidence of other oral keratosis	NO
				Evidence of oral lesions	NO
		Discharge Visit	08DEC2011	Heart	NL
				Lungs	NL
				Abdomen	NL
				Skin	NL
				Ears/Nose/Throat (ENT)	NL
				Neck	NL
				Evidence of leukoplakia	NO
				Evidence of other oral keratosis	NO
				Evidence of oral lesions	NO
14	35/F/Ca	Screening	11OCT2011	Heart	NL
				Lungs	NL
				Abdomen	NL
				Skin	NL
				Ears/Nose/Throat (ENT)	NL
				Neck	NL
				Evidence of leukoplakia	NO
				Evidence of other oral keratosis	NO
				Evidence of oral lesions	NO
		Discharge Visit	08DEC2011	Heart	NL
				Lungs	NL
				Abdomen	NL
				Skin	NL
				Ears/Nose/Throat (ENT)	NL
				Neck	NL
				Evidence of leukoplakia	NO
				Evidence of other oral keratosis	NO
				Evidence of oral lesions	NO

Listing 16.2.6.4
Oral Health and Physical Examination

Subject	Age/Sex/ Race	Visit	Date Obtained	Exam Item	Result
15	26/M/Ca	Screening	14OCT2011	Heart	NL
				Lungs	NL
				Abdomen	NL
				Skin	NL
				Ears/Nose/Throat (ENT)	NL
				Neck	NL
				Evidence of leukoplakia	NO
				Evidence of other oral keratosis	NO
				Evidence of oral lesions	NO
		Discharge Visit	08DEC2011	Heart	NL
				Lungs	NL
				Abdomen	NL
				Skin	NL
				Ears/Nose/Throat (ENT)	NL
				Neck	NL
				Evidence of leukoplakia	NO
				Evidence of other oral keratosis	NO
				Evidence of oral lesions	NO
16	53/M/Ca	Screening	13OCT2011	Heart	NL
				Lungs	NL
				Abdomen	NL
				Skin	NL
				Ears/Nose/Throat (ENT)	NL
				Neck	NL
				Evidence of leukoplakia	NO
				Evidence of other oral keratosis	NO
				Evidence of oral lesions	NO
		Discharge Visit	08DEC2011	Heart	NL
				Lungs	NL
				Abdomen	NL
				Skin	NL
				Ears/Nose/Throat (ENT)	NL

Listing 16.2.6.4
Oral Health and Physical Examination

Subject	Age/Sex/ Race	Visit	Date Obtained	Exam Item	Result
16	53/M/Ca	Discharge Visit	08DEC2011	Neck	NL
				Evidence of leukoplakia	NO
				Evidence of other oral keratosis	NO
				Evidence of oral lesions	NO
17	29/M/Ca	Screening	18OCT2011	Heart	NL
				Lungs	NL
				Abdomen	NL
				Skin	NL
				Ears/Nose/Throat (ENT)	NL
				Neck	NL
				Evidence of leukoplakia	NO
				Evidence of other oral keratosis	NO
				Evidence of oral lesions	NO
		Discharge Visit	22DEC2011	Heart	NL
				Lungs	NL
				Abdomen	NL
				Skin	NL
				Ears/Nose/Throat (ENT)	NL
				Neck	NL
				Evidence of leukoplakia	NO
				Evidence of other oral keratosis	NO
				Evidence of oral lesions	NO

16.2.7 Adverse Event Listings

Listing Number	Listing Title
16.2.7.1	Adverse Events
16.2.7.2	Serious Adverse Events
16.2.7.3	Adverse Events Leading to Cessation or Interruption of Usage

Listing 16.2.7.1
Adverse Events

{1} From the MedDRA dictionary, Version 13.1

{2} Relative Start/Stop Day is calculated relative to the date the subject signs the informed consent form, where Relative Start/Stop Day 1 refers to day of consent and Relative Start/Stop Day -1 refers to the day prior to the day of consent.
If start/stop date is on or after the date of consent, then Relative Start/Stop Day = start/stop date - enrollment date + 1.
If the start/stop date is before the date of enrollment, then Relative Start/Stop Day = start/stop date - enrollment date.

(3) Type: 0=ECG; 1=Lab; 2=Other

(4) Frequency: 0=Continuous; 1=Intermittent; 2=Single-Episode

{5} Severity: 0=Mild; 1=Moderate; 2=Severe; 3=Life-Threatening; 4=Death

(6) Treatment Required? 0=None; 1=Concomitant Meds; 2=Non-Drug Therapies; 3=Non-Drug Therapies and ConMeds; 4=Hospitalization; 5=Default

(7) Action Taken Select with Study Product and/or Subject: 0=None; 1=Interrupted; 2=Discontinued

(8) Relationship to Study Product: 0=Definite; 1=Probable; 2=Possible; 3=Unlikely; 4=Unrelated

(9) Serious adverse event: Y=Yes; N=No?

(10) Ongoing (at the end of the study): Y=Yes; N=No

(11) Outcome: 0=Resolved; 1=Resolved with sequelae; 2=Continuing; 3=Fatal; 4=Default

Adverse events will be temporally attributed to the last product received prior to adverse event occurrence.

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020701.SAS EXECUTED: 19AUG2012 15:40



Listing 16.2.7.2
Serious Adverse Events

{1} From the MedDRA dictionary, Version 13.1

{2} Relative Start/Stop Day is calculated relative to the date the subject signs the informed consent form, where Relative Start/Stop Day 1 refers to day of consent and Relative Start/Stop Day -1 refers to the day prior to the day of consent.
If start/stop date is on or after the date of consent, then Relative Start/Stop Day = start/stop date - enrollment date + 1.
If the start/stop date is before the date of enrollment, then Relative Start/Stop Day = start/stop date - enrollment date.

(3) Type: 0=ECG; 1=Lab; 2=Other

(4) Frequency: 0=Continuous; 1=Intermittent; 2=Single-Episode

{5} Severity: 0=Mild; 1=Moderate; 2=Severe; 3=Life-Threatening; 4=Death

(6) Treatment Required? 0=None; 1=Concomitant Meds; 2=Non-Drug Therapies; 3=Non-Drug Therapies and ConMeds; 4=Hospitalization; 5=Default

(7) Action Taken Select with Study Product and/or Subject: 0=None; 1=Interrupted; 2=Discontinued

(8) Relationship to Study Product: 0=Definite; 1=Probable; 2=Possible; 3=Unlikely; 4=Unrelated

(9) Serious adverse event: Y=Yes; N=No?

(10) Ongoing (at the end of the study): Y=Yes; N=No

(11) Outcome: 0=Resolved; 1=Resolved with sequelae; 2=Continuing; 3=Fatal; 4=Default

Note: Refer to page 1 of Listing 16.2.7.2 for footnotes.

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020701.SAS EXECUTED: 19AUG2012 15:40

Listing 16.2.7.2
Serious Adverse Events

Subject Product	Age/Sex/ Race	System Organ Class [1]/ Preferred Term [1]/ Onset Verbatim Term			Resolved Date/Time	Relative Start, Stop Day[2]					Frequ- ency [4]	Seve- Trt. rity Req		Acti- on[7]	Rela- tion- ship [8]	Seri- ous [9]	Ongo- ing [10]	Out- come [11]
		Type [3]	Type [3]	Type [3]		Type [3]	Type [3]	Type [3]	Type [3]	Type [3]								

There are no observations for this report.

Note: Refer to page 1 for footnotes.

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020701.SAS EXECUTED: 19AUG2012 15:40

Listing 16.2.7.3
Adverse Events Leading to Cessation or Interruption of Usage

{1} From the MedDRA dictionary, Version 13.1

{2} Relative Start/Stop Day is calculated relative to the date the subject signs the informed consent form, where Relative Start/Stop Day 1 refers to day of consent and Relative Start/Stop Day -1 refers to the day prior to the day of consent.
If start/stop date is on or after the date of consent, then Relative Start/Stop Day = start/stop date - enrollment date + 1.
If the start/stop date is before the date of enrollment, then Relative Start/Stop Day = start/stop date - enrollment date.

(3) Type: 0=ECG; 1=Lab; 2=Other

(4) Frequency: 0=Continuous; 1=Intermittent; 2=Single-Episode

{5} Severity: 0=Mild; 1=Moderate; 2=Severe; 3=Life-Threatening; 4=Death

(6) Treatment Required? 0=None; 1=Concomitant Meds; 2=Non-Drug Therapies; 3=Non-Drug Therapies and ConMeds; 4=Hospitalization; 5=Default

(7) Action Taken Select with Study Product and/or Subject: 0=None; 1=Interrupted; 2=Discontinued

(8) Relationship to Study Product: 0=Definite; 1=Probable; 2=Possible; 3=Unlikely; 4=Unrelated

(9) Serious adverse event: Y=Yes; N=No?

(10) Ongoing (at the end of the study): Y=Yes; N=No

(11) Outcome: 0=Resolved; 1=Resolved with sequelae; 2=Continuing; 3=Fatal; 4=Default

Note: Refer to page 1 of Listing 16.2.7.3 for footnotes.

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020701.SAS EXECUTED: 19AUG2012 15:40

Listing 16.2.7.3
Adverse Events Leading to Cessation or Interruption of Usage

Subject Product	Age/Sex/ Race	System Organ Class [1]/ Preferred Term [1]/ Onset Verbatim Term Date/Time			Resolved Date/Time	Relative Start, Stop Day[2]					Type [3]	Freq- uency [4]	Seve- Trt. rity Req		Acti- on[7]	Rela- tion- ship [8]	Seri- ous [9]	Ongo- ing [10]	Out- come [11]

There are no observations for this report.

Note: Refer to page 1 for footnotes.

PROGRAM: Z:/CDD/RJR/CSD1101/STAT/PROGRAM/LISTING/L16020701.SAS EXECUTED: 19AUG2012 15:40

16.2.8 Individual Laboratory Measurements and Vital Signs

Listing Number	Listing Title
16.2.8.1	Complete Blood Count
16.2.8.2	Comprehensive Metabolic Profile, Triglycerides, and Total Cholesterol
16.2.8.3	Urinalysis
16.2.9	Vital Signs

16.3 Electronic Source Forms

16.3.1 Electronic Source Forms for Deaths, Other Serious Adverse Events, and Withdrawals for Adverse Events

Not applicable; there were no deaths, other SAEs, or subject discontinuations due to AEs during this study.

16.3.2 Other Electronic Source Forms Submitted

Not applicable.

16.4 Individual Subject Data Listings

No subject profiles are being submitted as an appendix to this clinical study report. Individual subject profiles are available on request.

16.5 Bioanalytical Report

The Bioanalytical Report is provided on the following pages.



621 Rose Street
Lincoln, NE 68502 USA
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Tel: 402-476-2811
Toll Free: 800-776-1716
Fax: 402-939-0428

Assessment of Smokers' Nicotine Uptake and Urge to Smoke after Use of Smokeless Tobacco Products

LC-MS/MS Determination of Nicotine and Cotinine in Human Serum

Study: AA97220-01

Bioanalytical Final Report

R.J. Reynolds Tobacco Company
Product Integrity, Research and Development
Bowman Gray Technical Center
950 Reynolds Blvd.
Winston-Salem, NC 27105

Protocol CSD1101

Report Date: 10-Aug-2012

SIGNATURE


AUTHORIZATION



Kirk Newland, B.S.
Bioanalytical Principal Investigator

10-Aug-2012
Date

Approved by:



Eckhardt Schmidt, Ph.D.
Sponsor Contact
R.J. Reynolds Tobacco Company

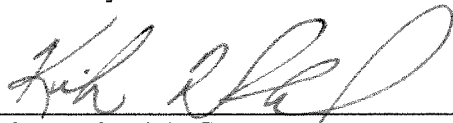
10-August 2012
Date

COMPLIANCE STATEMENT

This study was performed according to applicable GLP requirements and in compliance with Standard Operating Procedures (SOPs) in effect in the bioanalytical laboratory of Celerion, Lincoln, Nebraska. The SOPs are written based on the principles and requirements described in United States FDA Title 21 Code of Federal Regulations (CFR) Part 58.

To ensure the integrity of the reported data, the bioanalytical laboratory verified all results. The Quality Assurance unit of Celerion, Lincoln, Nebraska, audited the study. A Quality Assurance statement was then issued and is included in Attachment 1.

The data summaries, results, and conclusions in this bioanalytical report have been reviewed and were found to be consistent and scientifically rational. All deviations from the protocol and/or significant deviations from SOPs documented in this report have been reviewed and are scientifically valid.



Kirk Newland, B.S.
Bioanalytical Principal Investigator

10-Aug-2012
Date

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LIST OF ABBREVIATIONS

°C	degree Celsius (centigrade)
µg	microgram
AB	Applied Biosystems
API	atmospheric pressure ionization
BAM	bioanalytical method
BLK	blank
CDER	Center for Drug Evaluation and Research
CFR	Code of Federal Regulations
CV	coefficient of variation
Da	Dalton
EDTA	ethylenediaminetetraacetic acid
EXT	extraction
g	gram
GLP	good laboratory practices
h	hour
HDPE	high density polyethylene
HPLC	high performance liquid chromatography
ID	identification
INC	incongruous
INS	instrumentation
IS	internal standard
ISA	insufficient volume for full analysis
ISP	incomplete sample processing
ISR(s)	incurred sample reproducibility (samples)
ISV	insufficient volume
IVR	insufficient volume to reassay
L	litre, liter
LLOQ	lower limit of quantitation
LNK	Celerion, Lincoln site
M	molar
mg	milligram
mL	millilitre, milliliter
mol	mole
MS	mass spectrometry
MW	molecular weight
n	number of data
N/AP	not applicable
N/AV	not available
NFV	not full volume
ng	nanogram
No.	number
NU	not used
OECD	Organization for Economic Cooperation and Development
PD	Period
PE	Perkin Elmer
pg	picogram
QC	quality control
QCs	quality control samples
REF	reference
RI	reinjection
Rm.T.	room temperature
RR	reanalysis
RVL	remaining volume low
S.D.	standard deviation

SOP	standard operating procedure
SPE	solid-phase extraction
SST	system suitability test
STD	standard
Sub	subject
SVD	sample volume depleted
TBD	to be determined
Temp	temperature
UISR	Unacceptable Internal Standard Response
ULOQ	upper limit of quantitation
USP	US pharmacopeia
\bar{x}	mean

REASSAY DESCRIPTIONS

If study samples were identified according to the following table, they were reassayed if sufficient sample volume remained.

Reassay Term	Description based on the current global SOP GL-BIO-10603
AAR - 'Above the Accepted Range'	Identifies a sample whose calculated concentration is greater than the upper limit of quantitation (ULOQ).
BLQ - 'Below the Limit of Quantitation'	Identifies a sample whose calculated concentration is below the lower limit of quantitation (LLOQ).
DCU - 'Diluted Concentration Unreliable'	Identifies a sample with a concentration below the LLOQ before correction for the final dilution factor.
DCU (DFNR) - 'Diluted Concentration Unreliable (Dilution Factor Not Reliable)'	(b) (4)
EQB - 'Exceeding Quadratic Bounds'	Identifies a sample for which concentration data from a quadratic equation could not be obtained due to an inability to perform calculations.
HSR - 'Highest Standard Removed'	If the working range of the method is truncated as a result of the ULOQ standard being unavailable (rejected, lost in processing, etc.), then all samples with concentrations greater than the highest acceptable standard, are identified as 'highest standard removed.'
IIA - 'Incomplete Instrument Analysis'	Identifies a sample for which reliable data could not be obtained due to processing problems that occurred during injection or instrumental analysis and were documented by the analyst.
SSR - 'Sponsor Selected Reassays'	Reassays which are selected by the Sponsor.
BSS - 'Bracketing Study Samples'	Bracketing samples may be reassayed along with values requiring confirmation. The bracketing samples selected and the reason for including bracketing samples is documented prior to reassay.
ISF - 'Internal Standard Failure' OR UISR - 'Unacceptable Internal Standard Response'	Identifies a sample for which there is no internal standard (IS) response OR the IS response of the sample (unknown) is less than 50% or is greater than 180% of the determined mean IS response of evaluable standards and QCs.
LIP - 'Lost in Processing' OR ISP - 'Incomplete Sample Processing'	Identifies a sample for which concentration data could not be obtained due to, for example, technical problems (equipment failure, technical error, broken tubes, etc.).

Reassay Term	Description based on the current global SOP GL-BIO-10603
LSR - 'Lowest Standard Removed'	If the working range of the method is truncated as a result of the LLOQ standard being unavailable (rejected, lost in processing, etc.), all samples with concentrations below the lowest acceptable standard are identified 'lowest standard removed.'
Not Calculated	May be used to indicate statistics are not performed.
UCR - 'Unacceptable Chromatography'	Identifies a sample deemed by the reviewer to have exhibited chromatography that is unacceptable.
VRC – 'Value Requiring Confirmation'	From time to time, unexpected results may be obtained for individual study samples that appear inconsistent with the remaining data. Such values are defined as 'events' and are to be investigated.
Reassay Term	Description based on the current global SOP GL-BIO-10602
Fail	Identifies samples for which concentration data was not accepted because the batch did not meet batch acceptance criteria.

1. INTRODUCTION

Celerion in Lincoln, Nebraska, has determined the concentrations of nicotine and cotinine in human serum using high performance liquid chromatography (HPLC) with mass spectrometric detection. Study samples were received on 05-Jan-2012 as part of Protocol Number CSD1101, entitled, "Assessment of Smokers' Nicotine Uptake and Urge to Smoke after Use of Smokeless Tobacco Products," Celerion Study AA97220-01. Sample analysis was conducted between 09-Jan-2012 and 03-Feb-2012. [Table 1](#) provides a listing of all regressed batches and their respective analysis dates. This report provides the results and supporting documentation from the analysis of study samples as well as standard curve and quality control (QC) sample data. A copy of the sample analysis plan can be found in Attachment 2.

2. EXPERIMENTAL

2.1. Method and Materials

2.1.1. Analytical Method

(b) (4)

2.1.2. Reference Standards

	Analyte	Internal Standard (IS)
ID	S(-)-Nicotine	d ₃ -Nicotine
Source	(b) (4)	(b) (4)
Lot No.	FN092410-01	PR-21243
Celerion Correction Factor	1.0000	0.9761
Expiration Date	30-Sep-2015	27-Sep-2012
Celerion Asset ID	AS/005523, AS/005586	AS/005203
Storage Conditions*	Refrigerated (5°C)	Refrigerated (5°C)

	Analyte	Internal Standard (IS)
ID	(-)-Cotinine	(+/-)-Cotinine-d ₃
Source	(b) (4)	(b) (4)
Lot No.	FN051110-04	FN072307-01
Celerion Correction Factor	1.0000	1.0000
Expiration Date	31-May-2015	31-Jul-2012
Celerion Asset ID	AS/005576	AS/004157
Storage Conditions*	Refrigerated (5°C)	Refrigerated (5°C)

* Celerion reference standards are stored protected from light

Certificates of analysis are on file at Celerion Lincoln, Nebraska. See [Attachment 4](#) for certificate(s) of analysis.

2.1.3. Biological Matrix

Human serum was purchased from (b) (4). Human serum, free of significant interference, was used to prepare calibration standard and quality control (QC) samples.

2.1.4. Calibration Curve Standards and Quality Control Samples

(b) (4)



2.2. Study Samples

2.2.1. Sample Source and Date of Receipt

Study samples were received frozen on dry ice on 05-Jan-2012 from (b) (4) (b) (4).

2.2.2. Sample Storage and Stability

Study samples were stored from sample collection to the end of sample analysis at a nominal temperature of -80°C for a duration not exceeding 124 days.

Study samples were analyzed without exceeding short-term, freeze-thaw, or post-preparative stability. The following evaluations have been conducted:

Nicotine

Stability Summary	
Long-term stability	234 days in polypropylene tubes at -20°C 195 days in polypropylene tubes at -80°C
Short-term stability	26 hours in polypropylene tubes at ambient temperature under white light (for samples stored at -20°C and -80°C)
Cumulative short-term stability	53 hours in polypropylene tubes at ambient temperature under white light (total of all thaw cycles) for samples stored at -20°C, 78 hours in polypropylene tubes at ambient temperature under UV-shielded light (total of all thaw cycles) for samples stored at -80°C
Freeze-thaw stability	6 freeze (-20°C)-thaw (ambient temperature) cycles in polypropylene tubes under white light 6 freeze (-80°C)-thaw (ambient temperature) cycles in polypropylene tubes under UV-shielded light
Post-preparative stability	78 hours in a polypropylene 96 well plate at 5°C
Processed sample integrity	89 hours in a polypropylene 96 well plate at 5°C

Cotinine

Stability Summary	
Long-term stability	234 days in polypropylene tubes at -20°C 195 days in polypropylene tubes at -80°C
Short-term stability	26 hours in polypropylene tubes at ambient temperature under white light (for samples stored at -20°C and -80°C)
Cumulative short-term stability	53 hours in polypropylene tubes at ambient temperature under white light (total of all thaw cycles) for samples stored at -20°C, 78 hours in polypropylene tubes at ambient temperature under UV-shielded light (total of all thaw cycles) for samples stored at -80°C
Freeze-thaw stability	6 freeze (-20°C)-thaw (ambient temperature) cycles in polypropylene tubes under white light 6 freeze (-80°C)-thaw (ambient temperature) cycles in polypropylene tubes under UV-shielded light
Post-preparative stability	78 hours in a polypropylene 96 well plate at 5°C
Processed sample integrity	89 hours in a polypropylene 96 well plate at 5°C

Study samples were stored at a nominal temperature of -80°C for a duration not exceeding 124 days. Long-term stability of 234 days at -20°C has been established. Since the temperature at which study samples were stored differs from that of the stability assessment, an evaluation of freeze and thaw and long-term stability at a nominal temperature of -80°C will be conducted and reported as an amendment to the Validation Report. A copy of the amendment will be provided to the Sponsor.

2.2.3. Sample Summary

The Sponsor's protocol specifies up to 20 subjects would be recruited for randomization to have approximately 16 subjects complete the study. Sixteen timepoints were to be collected from each subject per test period.

	No. of Samples
Estimated per protocol/received	1600/1292
Not collected	308
Not requiring analysis (e.g., alternates, placebos, insufficient volume)	1
Total number of study samples analyzed	1291

All study samples are to be retained for a period specified in the service agreement, after which the Sponsor is to be contacted for further sample retention or disposition instructions.

3. RESULTS

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3.1. Batch Acceptance Criteria

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3.2. Quality Control Sample Analyses (Between-batch Precision and Accuracy)

Between-batch precision and accuracy results for QC samples prepared at low, medium, and high QC concentrations are summarized in [Table 2](#)^{*}.

3.3. Dilution Quality Control Sample Analyses

The accuracy of sample dilution was verified by the performance of dilution QC samples. At least 50% of the diluted QC samples (denoted with the dilution factor following the QC identifier) had to be within $\pm 15\%$ of the nominal concentration for the dilution scheme to be accepted. Results for dilution QC samples are summarized in [Table 2](#)^{*}.

3.4. Calibration Standard Concentrations

Back-calculated calibration curve standard concentrations are provided in [Table 3](#)^{*}.

3.5. Standard Curve Parameters

Standard curve parameters from 24 successful analytical batches for nicotine and 28 successful analytical batches for cotinine are provided in [Table 4](#)^{*}. A representative calibration curve is illustrated in [Figure 1](#) and [Figure 2](#).

3.6. Study Sample Concentrations

Study sample concentrations are provided in [Table 5](#).

Study samples, if any, which could not be repeated due to insufficient volume remaining are reported in [Table 5](#), Sample Comments column.

Study samples, if any, with no significant peak at the mass transition and retention time of nicotine, or with peak area ratios below that of the LLOQ standard, are reported as being below the limit of quantitation (BLQ).

During sample analysis, a predose sample from each subject at each period was extracted with internal standard to detect potential interference to determine a baseline nicotine concentration. As the subjects were smokers with only a 12 hour wash-out, measurable predose values were expected.

^{*} The summary of QC samples, calibration standards, and standard curve parameters for the incurred sample reproducibility batches [with the exception of Batch 39] is not located in [Table 2](#), [Table 3](#), and [Table 4](#). Those results are located in [Table 8](#).

3.7. Reassays

3.7.1. Reassays for Analytical Reasons

After initial analysis, upon which no value was obtained, study samples that were identified for reassay due to analytical reasons were reassayed without replication if sufficient sample volume remained. These samples are identified in [Table 6](#).

3.7.2. Reassays for Sample Investigation

There were no reassays conducted for sample investigation.

3.8. Known Metabolites, Isomers, and Endogenous Compounds

Selectivity from the tested metabolites not measured by the assay can be found in method validation report AA33664-05 in Attachment 3.

3.9. Incurred Sample Reproducibility

To demonstrate that the analysis of incurred clinical sample concentrations were reproducible for the bioanalytical method, 74 clinical samples were reassayed. The samples were selected from multiple analytical runs and across the concentration range for clinical samples from the study. The % Difference for each pair of original and repeat assay results were calculated. If the % Difference was $\leq 20\%$, the pair was considered to be a match. The method was considered to be reproducible if at least two thirds (2/3) of the pairs matched. The results from this evaluation are presented in [Table 7](#). These results demonstrate that 95.9% of the pairs matched for nicotine and 98.6% of the pairs matched for cotinine. The ISR testing demonstrated that the method is considered reproducible. The accuracy (%Theoretical) results for the calibration standards, QC samples, and standard curve parameters used for the incurred sample reproducibility are summarized in [Table 8](#).

4. RAW DATA AND CHROMATOGRAMS

The individual run reports for all accepted batches are presented in Attachment 5. Chromatograms from a minimum of 20% of the subjects are provided in Attachment 6. Calculated concentrations as displayed on the chromatograms resulting from the Analyst™ software may differ from the calculated concentrations derived from the Watson™ LIMS software. The Watson™ LIMS concentrations are the officially reviewed and accepted concentrations for the provided data.

5. ANALYTICAL NOTES

5.1. The following batches were not included in the data set.

<u>Batch</u>	<u>Analyte</u>	<u>Reason for Non-inclusion</u>
10	Cotinine	Batch 10 was reassayed as Batch 23 due to the beginning instrumentation evaluation not meeting acceptance criteria.
11	Nicotine	Batch 11 was reassayed as Batch 24 due to control blanks and internal standard spiked control blanks not meeting acceptance criteria.
11	Cotinine	Batch 11 was reassayed as Batch 25 due to control blanks and internal standard spiked control blanks not meeting acceptance criteria.
15	Nicotine / Cotinine	Batch 15 was reassayed as Batch 30 due to an extraction error.
34	Cotinine	Batch 34 was reassayed as Batch 36 due to unacceptable chromatography.
35	Nicotine / Cotinine	Batch 35 was reassayed as Batch 37 due to unacceptable chromatography.

5.2. The following batches were not included in the data set due to instrumentation issues. The issues were resolved, and the batches were reinjected.

<u>Batch</u>	<u>Analyte</u>	<u>Reason for Non-inclusion</u>
9	Nicotine / Cotinine	Batch 9 was re-injected as Batch 22 due to unacceptable chromatography.
28	Cotinine	Batch 28 was re-injected as Batch 34 due to unacceptable chromatography.
29	Nicotine / Cotinine	Batch 29 was re-injected as Batch 35 due to unacceptable chromatography.

5.3. The following sample had insufficient volume to assay. There was no reported value.

<u>Subject</u>	<u>Visit</u>	<u>Time Point</u>	<u>Sample Number</u>
13	6	Day 1 0.1667 hour	05104620001030

5.4. Batches 26, 27, 28, 31, 32, and 36 consisted of reassays for cotinine only. The batches were not regressed for nicotine.

5.5. When a sample was reassayed for only one compound and the reassay result for the other compound was not needed, the unneeded reassay result was deactivated as “Not Used” and was not reported.

5.6. During the naming of batches, number 21 was not used.

5.7. Event Investigation LNK-EIR-12-0027 was initiated due to an unexpected result on Batch 16. The batch had an excessive number of samples identified as unacceptable internal standard response, (UISR), for cotinine. Test injections confirmed the original observations. There was no impact on the study as the samples were successfully reassayed and reported in the data set.

5.7. Event Investigation LNK-EIR-12-0028 was initiated due to an unexpected result on

(b) (4)



5.8. Event Investigation LNK-EIR-12-0029 was initiated due to an unexpected nicotine result on Batch 11. The control blank, Injection #19, had an analyte peak that was greater than that of the Standard B. Additionally, a single Quality Control A sample, Injection 30, had a bias greater than 50% of nominal. The obvious spot contaminations were likely the result of an aliquoting error. Batch 11 was rejected due to the failure of the control blank contamination criteria. There was no further impact as the batch was successfully reassayed as Batch 24.

5.9. Deviation LNK-12-0028 from SOP AA33664-05, Section 7.2b, occurred on Batch 15 when a make-up spike of water was added to the standards. The make-up spike was to be added only to the QCs, blanks, and Standard A's. As the assay performance had not been assessed with the inadvertant addition of the water volume noted above, the batch was rejected and reperformed. There was no impact on the study.

5.10. DEV-LNK-12-0107 was documented to detail the deviation from the sample analysis plan for study AA97220-01. During the preparation of the sample analysis plan a typo occurred when the dilution QC was identified. As a result the concentration that was prepared was not appropriate for small dilution factors of 2 and 5 that were used in the study. To employ a DF of 2 and 5, the QC C was used instead. It should be noted that the dilution QC results consistently demonstrated accurate and precise performance of the dilution. Additionally, the incurred sample reproducibility testing, performed with samples that were diluted, confirmed the originally measured concentrations. Data from the method validation supports dilution integrity which brackets the concentrations measured within study AA97220-01; therefore, there was no impact on the validity of the reported results.

6. STORAGE OF THE STUDY RELATED MATERIALS

All raw data, associated data, and the report are archived by Celerion, according to the SOP in effect during the conduct of the study.

7. COMPUTER APPLICATION PROGRAMS

Computer application programs used to acquire and derive data for this study included Watson™ LIMS 7.3 and AB SCIEX Analyst™ 1.5.1. All regressions and calculations of concentrations were performed by Watson™ LIMS. Additionally, raw data was stored in electronic notebook system, Labnotes™ Web Client 1.10.4.

8. CONCLUSION

The objective of this bioanalytical study AA97220-01 was to determine concentrations of nicotine and cotinine using a validated LC-MS/MS method, in human serum samples taken throughout the clinical study CSD1101. It was concluded that the overall performance of the LC-MS/MS method was acceptable and that the results obtained were of the required integrity and quality. The data may be used for further interpretation.

9. REFERENCES

The supporting sample analysis plan, containing a list of current Celerion Standard Operating Procedures, and the current method validation report, can be found in Attachments 2 and 3, respectively.

TABLES

Table 1. Summary of Batches Performed

Analyte Name	Batch Number	Regression Status	Extraction Date	Assay Date	Description	Comment
Nicotine	1	Accepted	09-Jan-2012	09-Jan-2012	SUB 01 PD 1-4	OK
Nicotine	2	Accepted	09-Jan-2012	10-Jan-2012	SUB 01 PD 5 AND 02 PD 1-3	OK
Nicotine	3	Accepted	09-Jan-2012	09-Jan-2012	SUB 02 PD 4-5 AND 03 PD 1-2	OK
Nicotine	4	Accepted	09-Jan-2012	10-Jan-2012	SUB 03 PD 3-5 AND 04 PD 1	OK
Nicotine	5	Accepted	10-Jan-2012	10-Jan-2012	SUB 04 PD 2-5	OK
Nicotine	6	Accepted	10-Jan-2012	11-Jan-2012	SUB 05 PD 1-4	OK
Nicotine	7	Accepted	10-Jan-2012	10-Jan-2012	SUB 05 PD 5 AND 06 PD 1-3	OK
Nicotine	8	Accepted	10-Jan-2012	11-Jan-2012	SUB 06 PD 4-5, 07 PD 1, AND 08 PD 1	OK
Nicotine	10	Accepted	11-Jan-2012	12-Jan-2012	SUB 09 PD 1-4	OK
Nicotine	11	Rejected	12-Jan-2012	12-Jan-2012	SUB 09 PD 5 AND 10 PD 1-3	interference
Nicotine	12	Accepted	12-Jan-2012	13-Jan-2012	SUB 10 PD 4-5 AND 11 PD 1-2	OK
Nicotine	13	Accepted	12-Jan-2012	13-Jan-2012	SUB 11 PD 3-5 AND 12 PD 1	OK
Nicotine	14	Accepted	12-Jan-2012	14-Jan-2012	SUB 12 PD 2-5	OK
Nicotine	15	Rejected	13-Jan-2012	13-Jan-2012	SUB 13 PD 1-4	extraction error
Nicotine	16	Accepted	13-Jan-2012	14-Jan-2012	SUB 13 PD 5 AND 14 PD 1-3	OK
Nicotine	17	Accepted	17-Jan-2012	17-Jan-2012	SUB 14 PD 4-5 AND 15 PD 1-2	OK
Nicotine	18	Accepted	17-Jan-2012	18-Jan-2012	SUB 15 PD 3-5 AND 16 PD 1	OK
Nicotine	19	Accepted	17-Jan-2012	17-Jan-2012	SUB 16 PD 2-5	OK
Nicotine	20	Accepted	17-Jan-2012	18-Jan-2012	SUB 17 PD 1-4	OK
Nicotine	22	Accepted	11-Jan-2012	12-Jan-2012	RI of RUN_009, SUB 08 PD 2-5	OK
Nicotine	23	Accepted	17-Jan-2012	18-Jan-2012	RR FAILED COT RUN 10 AND REASSAYS (SUB 09 PD 1-4)	OK
Nicotine	24	Accepted	18-Jan-2012	18-Jan-2012	RR FAILED NIC RUN 11(SUB 09 PD 5 AND 10 PD 1-3)	OK
Nicotine	30	Accepted	24-Jan-2012	25-Jan-2012	RR FAILED RUN 15 (SUB 13 PD 1-4)	OK
Nicotine	33	Accepted	25-Jan-2012	26-Jan-2012	SUB 17 PD 5 + REASSAYS	OK

Analyte Name	Batch Number	Regression Status	Extraction Date	Assay Date	Description	Comment
Nicotine	37	Accepted	26-Jan-2012	26-Jan-2012	RR RUN 35 (RI RUN 29 (REASSAYS))	OK
Nicotine	38	Accepted	02-Feb-2012	02-Feb-2012	ISRS	OK
Nicotine	39	Accepted	02-Feb-2012	03-Feb-2012	ISRS AND REASSAYS	OK
Cotinine	1	Accepted	09-Jan-2012	09-Jan-2012	SUB 01 PD 1-4	OK
Cotinine	2	Accepted	09-Jan-2012	10-Jan-2012	SUB 01 PD 5 AND 02 PD 1-3	OK
Cotinine	3	Accepted	09-Jan-2012	09-Jan-2012	SUB 02 PD 4-5 AND 03 PD 1-2	OK
Cotinine	4	Accepted	09-Jan-2012	10-Jan-2012	SUB 03 PD 3-5 AND 04 PD 1	OK
Cotinine	5	Accepted	10-Jan-2012	10-Jan-2012	SUB 04 PD 2-5	OK
Cotinine	6	Accepted	10-Jan-2012	11-Jan-2012	SUB 05 PD 1-4	OK
Cotinine	7	Accepted	10-Jan-2012	10-Jan-2012	SUB 05 PD 5 AND 06 PD 1-3	OK
Cotinine	8	Accepted	10-Jan-2012	11-Jan-2012	SUB 06 PD 4-5, 07 PD 1, AND 08 PD 1	OK
Cotinine	10	Rejected	11-Jan-2012	12-Jan-2012	SUB 09 PD 1-4	sst failure-unstable response
Cotinine	11	Rejected	12-Jan-2012	12-Jan-2012	SUB 09 PD 5 AND 10 PD 1-3	interference
Cotinine	12	Accepted	12-Jan-2012	13-Jan-2012	SUB 10 PD 4-5 AND 11 PD 1-2	OK
Cotinine	13	Accepted	12-Jan-2012	13-Jan-2012	SUB 11 PD 3-5 AND 12 PD 1	OK
Cotinine	14	Accepted	12-Jan-2012	14-Jan-2012	SUB 12 PD 2-5	OK
Cotinine	15	Rejected	13-Jan-2012	13-Jan-2012	SUB 13 PD 1-4	extraction error
Cotinine	16	Accepted	13-Jan-2012	14-Jan-2012	SUB 13 PD 5 AND 14 PD 1-3	OK
Cotinine	17	Accepted	17-Jan-2012	17-Jan-2012	SUB 14 PD 4-5 AND 15 PD 1-2	OK
Cotinine	18	Accepted	17-Jan-2012	18-Jan-2012	SUB 15 PD 3-5 AND 16 PD 1	OK
Cotinine	19	Accepted	17-Jan-2012	17-Jan-2012	SUB 16 PD 2-5	OK
Cotinine	20	Accepted	17-Jan-2012	18-Jan-2012	SUB 17 PD 1-4	OK
Cotinine	22	Accepted	11-Jan-2012	12-Jan-2012	RI of RUN_009, SUB 08 PD 2-5	OK
Cotinine	23	Accepted	17-Jan-2012	18-Jan-2012	RR FAILED COT RUN 10 AND REASSAYS (SUB 09 PD 1-4)	OK
Cotinine	25	Accepted	18-Jan-2012	19-Jan-2012	RR FAILED COT RUN 11 (SUB 09 PD 5 AND 10 PD 1-3)	OK
Cotinine	26	Accepted	18-Jan-2012	19-Jan-2012	REASSAYS (COT ONLY)	OK
Cotinine	27	Accepted	23-Jan-2012	23-Jan-2012	REASSAYS (COT ONLY)	OK
Cotinine	30	Accepted	24-Jan-2012	25-Jan-2012	RR FAILED RUN 15 (SUB 13 PD 1-4)	OK

Analyte Name	Batch Number	Regression Status	Extraction Date	Assay Date	Description	Comment
Cotinine	31	Accepted	24-Jan-2012	25-Jan-2012	REASSAYS (COT ONLY)	OK
Cotinine	32	Accepted	25-Jan-2012	26-Jan-2012	REASSAYS (COT ONLY)	OK
Cotinine	33	Accepted	25-Jan-2012	26-Jan-2012	SUB 17 PD 5 + REASSAYS	OK
Cotinine	36	Accepted	26-Jan-2012	26-Jan-2012	RR RUN 34 (RI RUN 28 (REASSAYS (COT ONLY)))	OK
Cotinine	37	Accepted	26-Jan-2012	26-Jan-2012	RR RUN 35 (RI RUN 29 (REASSAYS))	OK
Cotinine	38	Accepted	02-Feb-2012	02-Feb-2012	ISRS	OK
Cotinine	39	Accepted	02-Feb-2012	03-Feb-2012	ISRS AND REASSAYS	OK

Table 2. Quality Control Sample Data (Between-batch Precision and Accuracy)

Nicotine

Assay Date	Batch Number	QC A 1.50 ng/mL	QC B 8.00 ng/mL	QC C 37.5 ng/mL	QC C DF2 37.5 ng/mL	QC C DF5 37.5 ng/mL
09-Jan-2012	1	1.56	8.03	39.5		
		1.58	8.10	39.0		
09-Jan-2012	3	1.64	7.26	35.3		
		1.45	7.57	36.6		
10-Jan-2012	2	1.45	7.77	39.7		
		1.57	7.84	38.3		
10-Jan-2012	4	1.33	7.49	37.8		
		1.44	7.55	36.2		
10-Jan-2012	5	1.38	8.02	39.0		
		1.57	7.85	38.7		
10-Jan-2012	7	1.47	7.33	36.9		
		1.39	7.78	36.8		
11-Jan-2012	6	1.63	7.83	39.4		
		1.55	7.81	39.1		
11-Jan-2012	8	1.43	7.33	38.6		
		~2.18	7.53	38.6		
12-Jan-2012	10	1.47	7.48	38.5		
		1.50	8.15	37.4		
12-Jan-2012	22	1.41	7.48	37.2		
		1.61	7.65	38.3		
13-Jan-2012	12	1.57	7.44	38.2		
		1.46	7.45	39.5		
13-Jan-2012	13	1.35	7.93	37.7		
		1.51	7.90	36.7		
14-Jan-2012	14	1.38	7.34	37.8		
		1.51	7.42	37.3		
14-Jan-2012	16	*1.36	7.45	36.2		
		1.56	7.58	*35.5		
17-Jan-2012	17	1.38	7.77	39.4		
		1.50	7.69	37.5		
17-Jan-2012	19	1.48	7.44	38.7		
		1.35	7.52	37.2		
18-Jan-2012	18	1.48	7.62	36.9		
		1.43	7.40	38.3		
18-Jan-2012	20	1.49	7.39	36.1		
		1.49	7.63	34.1		
18-Jan-2012	23	1.41	7.31	37.4		36.5
		1.50	7.51	40.1		36.4

Assay Date	Batch Number	QC A 1.50 ng/mL	QC B 8.00 ng/mL	QC C 37.5 ng/mL	QC C DF2 37.5 ng/mL	QC C DF5 37.5 ng/mL
18-Jan-2012	24	1.41	7.74	39.1		36.6
		1.54	7.63	38.5		
25-Jan-2012	30	1.59	7.20	38.3		
		1.45	7.80	37.2		
26-Jan-2012	33	1.30	7.64	39.6		37.6
		~1.27	7.35	37.8		38.0
						36.5
26-Jan-2012	37	1.28	7.28	36.8		36.1
		1.40	7.42	36.4		37.5
						36.3
03-Feb-2012	39	1.47	7.15	36.2	38.1	37.6
		1.40	~6.72	34.1	35.7	35.7
					38.0	36.6
Mean		1.48	7.57	37.7	37.3	36.8
S.D.		0.138	0.272	1.39	1.36	0.712
%CV		9.3	3.6	3.7	3.6	1.9
%Theoretical		98.7	94.6	100.5	99.5	98.1
%Bias		-1.3	-5.4	0.5	-0.5	-1.9
n		47	48	47	3	12

Reason Deactivated

* UISR

~ > 15%Bias

Cotinine

Assay Date	Batch Number	QC A 3.00 ng/mL	QC B 37.5 ng/mL	QC C 150 ng/mL	QC C DF2 150 ng/mL	QC C DF5 150 ng/mL
09-Jan-2012	1	3.13	38.6	155		
		3.24	38.8	~174		
09-Jan-2012	3	2.68	34.6	138		
		2.87	35.4	136		
10-Jan-2012	2	2.76	37.2	148		
		2.72	38.2	142		
10-Jan-2012	4	2.80	34.8	142		
		2.83	35.4	141		
10-Jan-2012	5	2.86	38.6	151		
		3.10	38.0	154		
10-Jan-2012	7	2.79	35.6	148		
		2.86	35.1	143		
11-Jan-2012	6	2.88	36.7	144		
		2.87	35.8	140		
11-Jan-2012	8	2.81	35.2	140		
		~4.07	35.5	141		
12-Jan-2012	22	2.96	37.2	146		
		2.98	37.7	149		
13-Jan-2012	12	2.85	36.6	141		
		2.83	36.0	147		
13-Jan-2012	13	2.81	35.9	148		
		2.65	37.0	139		
14-Jan-2012	14	2.76	35.6	141		
		3.05	35.4	142		
14-Jan-2012	16	*2.72	34.5	134		
		3.27	35.2	*141		
17-Jan-2012	17	3.10	36.2	152		
		2.95	37.0	143		
17-Jan-2012	19	2.84	36.7	148		
		2.82	35.6	144		
18-Jan-2012	18	2.75	35.0	*141		
		2.64	34.2	140		
18-Jan-2012	20	2.77	35.5	144		
		2.86	36.3	139		
18-Jan-2012	23	2.97	35.9	143		141
		2.93	35.1	149		141
						138
19-Jan-2012	25	2.79	37.2	142		143
		3.14	36.1	143		140
						146

Assay Date	Batch Number	QC A 3.00 ng/mL	QC B 37.5 ng/mL	QC C 150 ng/mL	QC C DF2 150 ng/mL	QC C DF5 150 ng/mL
19-Jan-2012	26	2.96	35.9	144		143
		2.97	35.3	142		136
						142
23-Jan-2012	27	2.81	34.9	140		140
		2.76	36.1	146		143
						135
25-Jan-2012	30	2.96	37.4	140		
		2.84	34.7	138		
25-Jan-2012	31	3.01	36.2	142		144
		2.79	35.7	148		135
						141
26-Jan-2012	32	3.10	36.5	143		141
		3.19	37.7	145		145
						143
26-Jan-2012	33	2.93	35.7	143		148
		2.67	35.8	152		146
						145
26-Jan-2012	36	3.02	37.2	141		145
		2.97	36.2	139		143
						145
26-Jan-2012	37	2.99	36.1	143		144
		3.10	38.1	148		143
						145
03-Feb-2012	39	2.97	34.1	140	140	137
		2.93	34.4	132	137	144
					139	140
Mean		2.93	36.1	144	139	142
S.D.		0.215	1.17	6.28	1.53	3.33
%CV		7.3	3.2	4.4	1.1	2.3
%Theoretical		97.7	96.3	96.0	92.7	94.7
%Bias		-2.3	-3.7	-4.0	-7.3	-5.3
n		55	56	54	3	30

Reason Deactivated

* UISR

~ > 15%Bias

Table 3. Back-calculated Calibration Curve Standard Concentrations

Nicotine

Assay Date	Batch Number	STD B 0.500 ng/mL	STD C 1.00 ng/mL	STD D 2.00 ng/mL	STD E 4.00 ng/mL	STD F 8.00 ng/mL	STD G 10.0 ng/mL	STD H 20.0 ng/mL	STD I 40.0 ng/mL	STD J 50.0 ng/mL
09-Jan-2012	1	0.487	1.03	2.16	3.85	7.96	9.43	19.9	43.0	47.4
09-Jan-2012	3	0.477	1.09	2.07	3.85	7.59	10.1	19.9	40.3	49.9
10-Jan-2012	2	0.498	1.01	2.01	3.91	7.98	10.0	20.4	40.8	48.5
10-Jan-2012	4	0.495	1.01	2.08	3.81	8.08	9.54	20.3	41.2	49.6
10-Jan-2012	5	0.501	0.989	1.99	4.07	8.23	10.1	19.7	39.2	49.4
10-Jan-2012	7	0.513	0.963	1.94	3.95	8.17	10.1	20.5	40.3	49.8
11-Jan-2012	6	0.484	1.04	2.09	3.98	7.79	10.2	20.0	41.0	46.8
11-Jan-2012	8	0.479	1.09	2.03	3.91	7.17	9.75	20.7	42.7	49.2
12-Jan-2012	10	*-0.0233	0.986	2.06	4.06	7.86	9.53	20.4	40.1	50.6
12-Jan-2012	22	0.494	0.972	2.21	4.02	8.14	9.69	19.4	39.9	48.9
13-Jan-2012	12	0.492	1.01	2.09	3.95	8.18	9.89	20.0	40.3	47.8
13-Jan-2012	13	0.504	0.978	2.05	3.84	8.23	9.88	21.0	39.5	48.9

Assay Date	Batch Number	STD B 0.500 ng/mL	STD C 1.00 ng/mL	STD D 2.00 ng/mL	STD E 4.00 ng/mL	STD F 8.00 ng/mL	STD G 10.0 ng/mL	STD H 20.0 ng/mL	STD I 40.0 ng/mL	STD J 50.0 ng/mL
14-Jan-2012	14	0.495	0.988	2.13	4.07	7.75	9.90	20.3	40.8	47.2
14-Jan-2012	16	0.485	1.05	2.08	3.81	7.83	10.6	20.3	39.9	46.9
17-Jan-2012	17	0.504	0.979	2.03	3.94	8.21	9.71	20.0	41.6	48.7
17-Jan-2012	19	0.495	0.975	2.20	3.95	8.13	9.69	19.5	39.4	50.0
18-Jan-2012	18	0.492	1.03	1.99	4.13	7.99	9.72	20.0	40.3	49.0
18-Jan-2012	20	0.474	1.11	2.03	3.88	8.01	9.66	20.2	40.3	48.8
18-Jan-2012	23	0.524	0.905	2.00	3.98	8.04	9.89	20.7	40.7	50.2
18-Jan-2012	24	0.495	1.01	2.06	3.97	7.67	9.99	20.6	41.0	48.2
25-Jan-2012	30	0.508	0.972	2.02	3.88	7.65	9.82	21.7	40.6	49.5
26-Jan-2012	33	0.520	0.929	1.98	3.92	7.80	10.2	20.1	42.6	49.7
26-Jan-2012	37	0.483	1.06	2.03	4.02	7.77	9.71	19.9	41.0	49.4
03-Feb-2012	39	0.506	0.987	1.92	4.12	7.73	10.2	20.1	40.5	50.1

Mean	0.496	1.01	2.05	3.95	7.92	9.89	20.2	40.7	48.9
S.D.	0.0130	0.0495	0.0722	0.0931	0.255	0.269	0.491	0.981	1.07
%CV	2.6	4.9	3.5	2.4	3.2	2.7	2.4	2.4	2.2
%Bias	-0.8	1.0	2.5	-1.3	-1.0	-1.1	1.0	1.8	-2.2
n	23	24	24	24	24	24	24	24	24

Reason Deactivated
 * Rejected

Cotinine

Assay Date	Batch Number	STD B 1.00 ng/mL	STD C 2.00 ng/mL	STD D 4.00 ng/mL	STD E 8.00 ng/mL	STD F 16.0 ng/mL	STD G 40.0 ng/mL	STD H 80.0 ng/mL	STD I 160 ng/mL	STD J 200 ng/mL
09-Jan-2012	1	0.949	2.23	4.00	7.76	15.7	37.8	79.2	172	195
09-Jan-2012	3	0.953	2.16	4.17	7.89	16.1	39.2	79.2	158	196
10-Jan-2012	2	0.982	2.10	3.91	7.97	15.8	39.2	79.8	166	198
10-Jan-2012	4	0.951	2.18	4.02	8.19	15.7	39.4	79.7	161	192
10-Jan-2012	5	0.925	2.24	4.32	7.75	15.6	40.4	79.2	154	193
10-Jan-2012	7	0.972	2.12	4.10	7.53	15.9	38.5	81.7	159	206
11-Jan-2012	6	0.966	2.12	4.18	7.75	15.3	39.4	82.2	159	200
11-Jan-2012	8	1.01	1.97	4.01	7.92	15.9	39.4	81.8	162	200
12-Jan-2012	22	0.982	2.02	4.22	8.07	15.9	39.2	79.0	161	196
13-Jan-2012	12	0.988	2.02	4.18	7.92	15.5	39.3	80.0	162	200
13-Jan-2012	13	0.972	2.11	4.03	7.90	16.1	38.7	82.0	157	199
14-Jan-2012	14	0.962	2.15	4.00	8.15	15.3	39.3	80.5	164	195
14-Jan-2012	16	0.942	2.19	4.10	8.38	15.9	39.8	80.6	153	187

Assay Date	Batch Number	STD B 1.00 ng/mL	STD C 2.00 ng/mL	STD D 4.00 ng/mL	STD E 8.00 ng/mL	STD F 16.0 ng/mL	STD G 40.0 ng/mL	STD H 80.0 ng/mL	STD I 160 ng/mL	STD J 200 ng/mL
17-Jan-2012	17	0.985	2.09	3.94	7.84	15.5	40.9	80.8	160	201
17-Jan-2012	19	0.975	2.10	4.05	8.02	15.4	39.2	78.9	159	207
18-Jan-2012	18	0.951	2.16	4.14	8.11	15.9	38.8	78.1	160	197
18-Jan-2012	20	0.978	2.11	3.85	8.34	15.5	39.5	79.5	159	203
18-Jan-2012	23	0.971	2.11	4.07	8.01	15.6	38.5	81.6	160	200
19-Jan-2012	25	0.989	1.99	4.20	8.11	15.8	39.3	79.8	160	197
19-Jan-2012	26	0.946	2.21	4.07	8.09	15.1	38.9	79.4	162	199
23-Jan-2012	27	0.943	2.23	4.01	8.07	15.9	40.0	77.3	159	195
25-Jan-2012	30	0.985	2.04	4.20	7.77	15.0	39.3	80.1	165	204
25-Jan-2012	31	0.970	2.09	4.15	7.94	15.8	39.8	78.6	158	200
26-Jan-2012	32	0.978	2.06	4.11	8.10	15.9	38.3	80.2	161	198
26-Jan-2012	33	0.987	2.06	4.09	7.47	16.2	40.1	80.3	164	197
26-Jan-2012	36	0.986	2.00	4.24	7.99	16.0	39.2	79.7	160	195
26-Jan-2012	37	1.00	1.97	4.19	7.68	16.0	40.0	80.5	162	198

Assay Date	Batch Number	STD B 1.00 ng/mL	STD C 2.00 ng/mL	STD D 4.00 ng/mL	STD E 8.00 ng/mL	STD F 16.0 ng/mL	STD G 40.0 ng/mL	STD H 80.0 ng/mL	STD I 160 ng/mL	STD J 200 ng/mL
03-Feb-2012	39	0.971	2.05	4.34	7.68	15.9	38.7	81.5	160	196
Mean		0.970	2.10	4.10	7.94	15.7	39.3	80.0	161	198
S.D.		0.0195	0.0791	0.116	0.218	0.304	0.657	1.21	3.61	4.17
%CV		2.0	3.8	2.8	2.7	1.9	1.7	1.5	2.2	2.1
%Bias		-3.0	5.0	2.5	-0.8	-1.9	-1.8	0.0	0.6	-1.0
n		28	28	28	28	28	28	28	28	28

Table 4. Standard Curve Parameters

Nicotine

Assay Date	Batch Number	Slope	Intercept	R-Squared
09-Jan-2012	1	0.706122544	0.0132239810	0.9965
09-Jan-2012	3	0.259548055	0.0106852516	0.9973
10-Jan-2012	2	0.716089655	-0.00293934828	0.9996
10-Jan-2012	4	0.260866894	0.0124750339	0.9987
10-Jan-2012	5	0.696412744	0.0384715211	0.9996
10-Jan-2012	7	0.254207883	0.00947099876	0.9993
11-Jan-2012	6	0.716132054	-0.0162250449	0.9982
11-Jan-2012	8	0.246720179	0.0230351250	0.9951
12-Jan-2012	10	0.708255787	0.0164747051	0.9991
12-Jan-2012	22	0.723874052	0.00863872549	0.9975
13-Jan-2012	12	0.256855346	0.0112593082	0.9991
13-Jan-2012	13	0.244052401	0.00889914748	0.9989
14-Jan-2012	14	0.247933629	0.00838375105	0.9983
14-Jan-2012	16	0.723699366	0.0318205540	0.9974
17-Jan-2012	17	0.723232570	0.0244840477	0.9992
17-Jan-2012	19	0.259302097	-0.00805895441	0.9978
18-Jan-2012	18	0.715210071	0.0285499574	0.9994
18-Jan-2012	20	0.262207671	-0.00561512211	0.9970
18-Jan-2012	23	0.249250098	0.00212399812	0.9978
18-Jan-2012	24	0.250166952	-0.00152576226	0.9990
25-Jan-2012	30	0.247809309	-0.00463144691	0.9979
26-Jan-2012	33	0.242628582	0.0190083910	0.9979
26-Jan-2012	37	0.249318880	0.0108938964	0.9987
03-Feb-2012	39	0.254702648	0.00501091336	0.9992
Mean		0.425608311	0.0101630678	0.9983
S.D.		0.228576868	0.0132161226	0.0011
%CV		53.7	130.0	0.1
n		24	24	24

Cotinine

Assay Date	Batch Number	Slope	Intercept	R-Squared
09-Jan-2012	1	0.0260479328	0.00240539176	0.9956
09-Jan-2012	3	0.00783155364	0.000706265426	0.9981
10-Jan-2012	2	0.0266682459	0.00482954985	0.9991
10-Jan-2012	4	0.00772786708	0.00000461928311	0.9977
10-Jan-2012	5	0.0268358948	0.00246679451	0.9949
10-Jan-2012	7	0.00794761038	0.000790216638	0.9981
11-Jan-2012	6	0.0276749144	0.00188251753	0.9983
11-Jan-2012	8	0.00781082820	0.00147170672	0.9998
12-Jan-2012	22	0.0525152187	0.00518386732	0.9993
13-Jan-2012	12	0.00768905581	0.00122379494	0.9993
13-Jan-2012	13	0.00747387357	0.00210444953	0.9990
14-Jan-2012	14	0.00763950541	0.000865320369	0.9981
14-Jan-2012	16	0.0555866526	0.00134057930	0.9966
17-Jan-2012	17	0.0559404647	0.00405311285	0.9992
17-Jan-2012	19	0.00769353939	0.00149722429	0.9989
18-Jan-2012	18	0.0578282957	0.0107594418	0.9980
18-Jan-2012	20	0.00775923455	0.000518576596	0.9986
18-Jan-2012	23	0.00750004739	0.000779203134	0.9989
19-Jan-2012	25	0.00771947342	0.000102958693	0.9994
19-Jan-2012	26	0.00769986220	0.000194605502	0.9970
23-Jan-2012	27	0.00774886626	0.00122351977	0.9970
25-Jan-2012	30	0.00748808478	0.00143130183	0.9984
25-Jan-2012	31	0.00754013477	0.000336911067	0.9992
26-Jan-2012	32	0.0615922188	0.00478093043	0.9993
26-Jan-2012	33	0.00747184661	0.000880990205	0.9989
26-Jan-2012	36	0.0616700072	0.00623567958	0.9992
26-Jan-2012	37	0.00753042022	-0.000403873893	0.9993
03-Feb-2012	39	0.00759048648	-0.000212390581	0.9980
Mean		0.0210793620	0.00205190230	0.9983
S.D.		0.0205556412	0.00244365356	0.0012
%CV		97.5	119.1	0.1
n		28	28	28

Table 5. Study Sample Concentrations

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	1	1	Pre-0	1	0.558	94.6	ng/mL		5104620000065	OK
CSD1101	1	1	0	2	2.48	93.9	ng/mL		5104620000066	OK
CSD1101	1	1	3	3	11.8	100	ng/mL		5104620000067	OK
CSD1101	1	1	5	4	15.1	96.5	ng/mL		5104620000068	OK
CSD1101	1	1	7.5	5	21.9	98.7	ng/mL		5104620000069	OK
CSD1101	1	1	10	6	21.5	99.1	ng/mL		5104620000070	OK
CSD1101	1	1	15	7	18.0	115	ng/mL		5104620000071	OK
CSD1101	1	1	20	8	16.6	115	ng/mL		5104620000072	OK
CSD1101	1	1	30	9	13.6	112	ng/mL		5104620000073	OK
CSD1101	1	1	45	10	9.79	114	ng/mL		5104620000074	OK
CSD1101	1	1	60	11	8.78	124	ng/mL		5104620000075	OK
CSD1101	1	1	75	12	7.53	120	ng/mL		5104620000076	OK
CSD1101	1	1	90	13	6.65	124	ng/mL		5104620000077	OK
CSD1101	1	1	120	14	5.06	115	ng/mL		5104620000078	OK
CSD1101	1	1	150	15	4.36	121	ng/mL		5104620000079	OK
CSD1101	1	1	180	16	3.56	111	ng/mL		5104620000080	OK
CSD1101	1	2	Pre-0	1	BLQ<(0.500)	79.4	ng/mL		5104620000049	OK
CSD1101	1	2	0	2	BLQ<(0.500)	90.0	ng/mL		5104620000050	OK
CSD1101	1	2	3	3	0.626	76.2	ng/mL		5104620000051	OK
CSD1101	1	2	5	4	0.949	80.8	ng/mL		5104620000052	OK
CSD1101	1	2	7.5	5	1.50	80.6	ng/mL		5104620000053	OK

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	1	2	10	6	1.58	77.7	ng/mL		5104620000054	OK
CSD1101	1	2	15	7	1.42	81.2	ng/mL		5104620000055	OK
CSD1101	1	2	20	8	1.27	81.7	ng/mL		5104620000056	OK
CSD1101	1	2	30	9	1.24	75.9	ng/mL		5104620000057	OK
CSD1101	1	2	45	10	1.34	83.7	ng/mL		5104620000058	OK
CSD1101	1	2	60	11	1.37	86.2	ng/mL		5104620000059	OK
CSD1101	1	2	75	12	1.31	86.9	ng/mL		5104620000060	OK
CSD1101	1	2	90	13	1.25	84.2	ng/mL		5104620000061	OK
CSD1101	1	2	120	14	1.07	83.0	ng/mL		5104620000062	OK
CSD1101	1	2	150	15	0.802	77.6	ng/mL		5104620000063	OK
CSD1101	1	2	180	16	0.672	73.2	ng/mL		5104620000064	OK
CSD1101	1	3	Pre-0	1	0.589	98.6	ng/mL		5104620000033	OK
CSD1101	1	3	0	2	0.569	99.4	ng/mL		5104620000034	OK
CSD1101	1	3	3	3	0.579	96.6	ng/mL		5104620000035	OK
CSD1101	1	3	5	4	1.19	100	ng/mL		5104620000036	OK
CSD1101	1	3	7.5	5	1.91	94.3	ng/mL		5104620000037	OK
CSD1101	1	3	10	6	2.89	97.7	ng/mL		5104620000038	OK
CSD1101	1	3	15	7	2.75	99.3	ng/mL		5104620000039	OK
CSD1101	1	3	20	8	2.94	105	ng/mL		5104620000040	OK
CSD1101	1	3	30	9	2.63	106	ng/mL		5104620000041	OK
CSD1101	1	3	45	10	2.41	112	ng/mL		5104620000042	OK
CSD1101	1	3	60	11	2.09	109	ng/mL		5104620000043	OK
CSD1101	1	3	75	12	1.88	108	ng/mL		5104620000044	OK
CSD1101	1	3	90	13	1.62	106	ng/mL		5104620000045	OK

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	1	3	120	14	1.33	97.9	ng/mL		5104620000046	OK
CSD1101	1	3	150	15	1.08	91.4	ng/mL		5104620000047	OK
CSD1101	1	3	180	16	0.949	92.8	ng/mL		5104620000048	OK
CSD1101	1	4	Pre-0	1	0.612	118	ng/mL		5104620000017	OK
CSD1101	1	4	0	2	0.534	110	ng/mL		5104620000018	OK
CSD1101	1	4	3	3	0.519	113	ng/mL		5104620000019	OK
CSD1101	1	4	5	4	0.631	116	ng/mL		5104620000020	OK
CSD1101	1	4	7.5	5	0.878	115	ng/mL		5104620000021	OK
CSD1101	1	4	10	6	0.917	112	ng/mL		5104620000022	OK
CSD1101	1	4	15	7	1.10	110	ng/mL		5104620000023	OK
CSD1101	1	4	20	8	1.16	112	ng/mL		5104620000024	OK
CSD1101	1	4	30	9	1.27	111	ng/mL		5104620000025	OK
CSD1101	1	4	45	10	1.63	122	ng/mL		5104620000026	OK
CSD1101	1	4	60	11	1.74	114	ng/mL		5104620000027	OK
CSD1101	1	4	75	12	1.83	111	ng/mL		5104620000028	OK
CSD1101	1	4	90	13	1.53	115	ng/mL		5104620000029	OK
CSD1101	1	4	120	14	1.70	112	ng/mL		5104620000030	OK
CSD1101	1	4	150	15	1.14	106	ng/mL		5104620000031	OK
CSD1101	1	4	180	16	1.05	99.5	ng/mL		5104620000032	OK
CSD1101	1	5	Pre-0	1	0.585	114	ng/mL		5104620000001	OK
CSD1101	1	5	0	2	0.591	113	ng/mL		5104620000002	OK
CSD1101	1	5	3	3	0.567	111	ng/mL		5104620000003	OK
CSD1101	1	5	5	4	0.743	103	ng/mL		5104620000004	OK
CSD1101	1	5	7.5	5	0.968	104	ng/mL		5104620000005	OK

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	1	5	10	6	1.70	111	ng/mL		5104620000006	OK
CSD1101	1	5	15	7	2.89	103	ng/mL		5104620000007	OK
CSD1101	1	5	20	8	3.65	110	ng/mL		5104620000008	OK
CSD1101	1	5	30	9	4.49	120	ng/mL		5104620000009	OK
CSD1101	1	5	45	10	3.90	110	ng/mL		5104620000010	OK
CSD1101	1	5	60	11	4.14	133	ng/mL		5104620000011	OK
CSD1101	1	5	75	12	3.93	132	ng/mL		5104620000012	OK
CSD1101	1	5	90	13	3.29	120	ng/mL		5104620000013	OK
CSD1101	1	5	120	14	2.62	124	ng/mL		5104620000014	OK
CSD1101	1	5	150	15	2.12	117	ng/mL		5104620000015	OK
CSD1101	1	5	180	16	1.82	120	ng/mL		5104620000016	OK
CSD1101	2	1	Pre-0	1	BLQ<(0.500)	98.4	ng/mL		5104620000145	OK
CSD1101	2	1	0	2	BLQ<(0.500)	98.7	ng/mL		5104620000146	OK
CSD1101	2	1	3	3	8.28	102	ng/mL		5104620000147	OK
CSD1101	2	1	5	4	17.0	104	ng/mL		5104620000148	OK
CSD1101	2	1	7.5	5	19.9	111	ng/mL		5104620000149	OK
CSD1101	2	1	10	6	13.0	103	ng/mL		5104620000150	OK
CSD1101	2	1	15	7	10.1	105	ng/mL		5104620000151	OK
CSD1101	2	1	20	8	7.88	109	ng/mL		5104620000152	OK
CSD1101	2	1	30	9	6.76	115	ng/mL		5104620000153	OK
CSD1101	2	1	45	10	4.82	109	ng/mL		5104620000154	OK
CSD1101	2	1	60	11	4.32	111	ng/mL		5104620000155	OK
CSD1101	2	1	75	12	3.39	102	ng/mL		5104620000156	OK
CSD1101	2	1	90	13	3.37	106	ng/mL		5104620000157	OK

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	2	1	120	14	2.67	104	ng/mL		5104620000158	OK
CSD1101	2	1	150	15	2.36	108	ng/mL		5104620000159	OK
CSD1101	2	1	180	16	1.90	102	ng/mL		5104620000160	OK
CSD1101	2	2	Pre-0	1	BLQ<(0.500)	95.1	ng/mL		5104620000129	OK
CSD1101	2	2	0	2	BLQ<(0.500)	93.1	ng/mL		5104620000130	OK
CSD1101	2	2	3	3	BLQ<(0.500)	92.5	ng/mL		5104620000131	OK
CSD1101	2	2	5	4	0.626	94.5	ng/mL		5104620000132	OK
CSD1101	2	2	7.5	5	1.23	89.6	ng/mL		5104620000133	OK
CSD1101	2	2	10	6	1.82	89.3	ng/mL		5104620000134	OK
CSD1101	2	2	15	7	1.64	91.5	ng/mL		5104620000135	OK
CSD1101	2	2	20	8	1.56	90.1	ng/mL		5104620000136	OK
CSD1101	2	2	30	9	1.55	96.8	ng/mL		5104620000137	OK
CSD1101	2	2	45	10	1.66	97.7	ng/mL		5104620000138	OK
CSD1101	2	2	60	11	1.55	95.3	ng/mL		5104620000139	OK
CSD1101	2	2	75	12	1.76	99.0	ng/mL		5104620000140	OK
CSD1101	2	2	90	13	1.25	98.0	ng/mL		5104620000141	OK
CSD1101	2	2	120	14	0.984	97.8	ng/mL		5104620000142	OK
CSD1101	2	2	150	15	0.772	92.6	ng/mL		5104620000143	OK
CSD1101	2	2	180	16	0.767	88.3	ng/mL		5104620000144	OK
CSD1101	2	3	Pre-0	1	0.659	122	ng/mL		5104620000113	OK
CSD1101	2	3	0	2	0.584	119	ng/mL		5104620000114	OK
CSD1101	2	3	3	3	0.619	117	ng/mL		5104620000115	OK
CSD1101	2	3	5	4	0.655	115	ng/mL		5104620000116	OK
CSD1101	2	3	7.5	5	0.868	114	ng/mL		5104620000117	OK

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	2	3	10	6	1.12	112	ng/mL		5104620000118	OK
CSD1101	2	3	15	7	1.34	116	ng/mL		5104620000119	OK
CSD1101	2	3	20	8	1.86	112	ng/mL		5104620000120	OK
CSD1101	2	3	30	9	2.04	116	ng/mL		5104620000121	OK
CSD1101	2	3	45	10	2.00	123	ng/mL		5104620000122	OK
CSD1101	2	3	60	11	2.16	123	ng/mL		5104620000123	OK
CSD1101	2	3	75	12	2.06	127	ng/mL		5104620000124	OK
CSD1101	2	3	90	13	1.72	130	ng/mL		5104620000125	OK
CSD1101	2	3	120	14	1.33	122	ng/mL		5104620000126	OK
CSD1101	2	3	150	15	1.32	124	ng/mL		5104620000127	OK
CSD1101	2	3	180	16	0.942	123	ng/mL		5104620000128	OK
CSD1101	2	4	Pre-0	1	0.541	116	ng/mL		5104620000097	OK
CSD1101	2	4	0	2	0.509	114	ng/mL		5104620000098	OK
CSD1101	2	4	3	3	1.06	113	ng/mL		5104620000099	OK
CSD1101	2	4	5	4	1.54	117	ng/mL		5104620000100	OK
CSD1101	2	4	7.5	5	1.90	114	ng/mL		5104620000101	OK
CSD1101	2	4	10	6	2.24	112	ng/mL		5104620000102	OK
CSD1101	2	4	15	7	3.33	110	ng/mL		5104620000103	OK
CSD1101	2	4	20	8	5.44	114	ng/mL		5104620000104	OK
CSD1101	2	4	30	9	7.89	118	ng/mL		5104620000105	OK
CSD1101	2	4	45	10	8.87	131	ng/mL		5104620000106	OK
CSD1101	2	4	60	11	6.96	138	ng/mL		5104620000107	OK
CSD1101	2	4	75	12	5.70	137	ng/mL		5104620000108	OK
CSD1101	2	4	90	13	4.60	137	ng/mL		5104620000109	OK

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	2	4	120	14	3.53	140	ng/mL		5104620000110	OK
CSD1101	2	4	150	15	2.61	132	ng/mL		5104620000111	OK
CSD1101	2	4	180	16	2.45	125	ng/mL		5104620000112	OK
CSD1101	2	5	Pre-0	1	0.512	111	ng/mL		5104620000081	OK
CSD1101	2	5	0	2	0.536	109	ng/mL		5104620000082	OK
CSD1101	2	5	3	3	0.537	107	ng/mL		5104620000083	OK
CSD1101	2	5	5	4	0.519	104	ng/mL		5104620000084	OK
CSD1101	2	5	7.5	5	0.723	107	ng/mL		5104620000085	OK
CSD1101	2	5	10	6	0.994	105	ng/mL		5104620000086	OK
CSD1101	2	5	15	7	1.15	107	ng/mL		5104620000087	OK
CSD1101	2	5	20	8	1.48	108	ng/mL		5104620000088	OK
CSD1101	2	5	30	9	1.42	105	ng/mL		5104620000089	OK
CSD1101	2	5	45	10	1.44	106	ng/mL		5104620000090	OK
CSD1101	2	5	60	11	1.56	114	ng/mL		5104620000091	OK
CSD1101	2	5	75	12	1.62	110	ng/mL		5104620000092	OK
CSD1101	2	5	90	13	1.46	109	ng/mL		5104620000093	OK
CSD1101	2	5	120	14	1.34	115	ng/mL		5104620000094	OK
CSD1101	2	5	150	15	1.07	114	ng/mL		5104620000095	OK
CSD1101	2	5	180	16	0.923	109	ng/mL		5104620000096	OK
CSD1101	3	1	Pre-0	1	3.05	288	ng/mL		5104620000225	OK
CSD1101	3	1	0	2	6.05	269	ng/mL		5104620000226	OK
CSD1101	3	1	3	3	7.15	281	ng/mL		5104620000227	OK
CSD1101	3	1	5	4	13.2	281	ng/mL		5104620000228	OK
CSD1101	3	1	7.5	5	.	.	ng/mL	Not Received	5104620000229	Not Received

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	3	1	10	6	.	.	ng/mL	Not Received	5104620000230	Not Received
CSD1101	3	1	15	7	16.2	283	ng/mL		5104620000231	OK
CSD1101	3	1	20	8	15.8	279	ng/mL		5104620000232	OK
CSD1101	3	1	30	9	13.3	274	ng/mL		5104620000233	OK
CSD1101	3	1	45	10	12.8	276	ng/mL		5104620000234	OK
CSD1101	3	1	60	11	11.4	277	ng/mL		5104620000235	OK
CSD1101	3	1	75	12	10.7	279	ng/mL		5104620000236	OK
CSD1101	3	1	90	13	9.20	277	ng/mL		5104620000237	OK
CSD1101	3	1	120	14	11.0	267	ng/mL		5104620000238	OK
CSD1101	3	1	150	15	8.21	274	ng/mL		5104620000239	OK
CSD1101	3	1	180	16	7.00	260	ng/mL		5104620000240	OK
CSD1101	3	2	Pre-0	1	3.16	236	ng/mL		5104620000209	OK
CSD1101	3	2	0	2	2.84	244	ng/mL		5104620000210	OK
CSD1101	3	2	3	3	3.37	248	ng/mL		5104620000211	OK
CSD1101	3	2	5	4	3.40	241	ng/mL		5104620000212	OK
CSD1101	3	2	7.5	5	3.65	241	ng/mL		5104620000213	OK
CSD1101	3	2	10	6	3.70	242	ng/mL		5104620000214	OK
CSD1101	3	2	15	7	3.90	237	ng/mL		5104620000215	OK
CSD1101	3	2	20	8	4.71	245	ng/mL		5104620000216	OK
CSD1101	3	2	30	9	5.42	243	ng/mL		5104620000217	OK
CSD1101	3	2	45	10	6.46	247	ng/mL		5104620000218	OK
CSD1101	3	2	60	11	5.33	248	ng/mL		5104620000219	OK
CSD1101	3	2	75	12	5.16	238	ng/mL		5104620000220	OK
CSD1101	3	2	90	13	5.04	242	ng/mL		5104620000221	OK

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	3	2	120	14	5.15	236	ng/mL		5104620000222	OK
CSD1101	3	2	150	15	4.31	239	ng/mL		5104620000223	OK
CSD1101	3	2	180	16	4.20	234	ng/mL		5104620000224	OK
CSD1101	3	3	Pre-0	1	2.48	234	ng/mL		5104620000193	OK
CSD1101	3	3	0	2	2.11	239	ng/mL		5104620000194	OK
CSD1101	3	3	3	3	2.51	249	ng/mL		5104620000195	OK
CSD1101	3	3	5	4	3.04	241	ng/mL		5104620000196	OK
CSD1101	3	3	7.5	5	2.36	235	ng/mL		5104620000197	OK
CSD1101	3	3	10	6	2.69	231	ng/mL		5104620000198	OK
CSD1101	3	3	15	7	3.22	232	ng/mL		5104620000199	OK
CSD1101	3	3	20	8	4.41	242	ng/mL		5104620000200	OK
CSD1101	3	3	30	9	4.79	235	ng/mL		5104620000201	OK
CSD1101	3	3	45	10	5.48	240	ng/mL		5104620000202	OK
CSD1101	3	3	60	11	5.16	234	ng/mL		5104620000203	OK
CSD1101	3	3	75	12	5.25	242	ng/mL		5104620000204	OK
CSD1101	3	3	90	13	4.93	235	ng/mL		5104620000205	OK
CSD1101	3	3	120	14	4.73	241	ng/mL		5104620000206	OK
CSD1101	3	3	150	15	4.04	231	ng/mL		5104620000207	OK
CSD1101	3	3	180	16	3.56	229	ng/mL		5104620000208	OK
CSD1101	3	4	Pre-0	1	2.26	250	ng/mL		5104620000177	OK
CSD1101	3	4	0	2	2.56	246	ng/mL		5104620000178	OK
CSD1101	3	4	3	3	2.19	247	ng/mL		5104620000179	OK
CSD1101	3	4	5	4	2.40	247	ng/mL		5104620000180	OK
CSD1101	3	4	7.5	5	3.03	236	ng/mL		5104620000181	OK

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	3	4	10	6	3.20	239	ng/mL		5104620000182	OK
CSD1101	3	4	15	7	3.71	233	ng/mL		5104620000183	OK
CSD1101	3	4	20	8	3.92	235	ng/mL		5104620000184	OK
CSD1101	3	4	30	9	4.33	237	ng/mL		5104620000185	OK
CSD1101	3	4	45	10	4.72	252	ng/mL		5104620000186	OK
CSD1101	3	4	60	11	3.96	236	ng/mL		5104620000187	OK
CSD1101	3	4	75	12	4.22	239	ng/mL		5104620000188	OK
CSD1101	3	4	90	13	4.07	225	ng/mL		5104620000189	OK
CSD1101	3	4	120	14	3.77	237	ng/mL		5104620000190	OK
CSD1101	3	4	150	15	3.43	236	ng/mL		5104620000191	OK
CSD1101	3	4	180	16	2.88	236	ng/mL		5104620000192	OK
CSD1101	3	5	Pre-0	1	2.09	254	ng/mL		5104620000161	OK
CSD1101	3	5	0	2	2.23	257	ng/mL		5104620000162	OK
CSD1101	3	5	3	3	2.10	252	ng/mL		5104620000163	OK
CSD1101	3	5	5	4	2.00	263	ng/mL		5104620000164	OK
CSD1101	3	5	7.5	5	2.26	258	ng/mL		5104620000165	OK
CSD1101	3	5	10	6	2.73	253	ng/mL		5104620000166	OK
CSD1101	3	5	15	7	3.21	235	ng/mL		5104620000167	OK
CSD1101	3	5	20	8	3.43	250	ng/mL		5104620000168	OK
CSD1101	3	5	30	9	4.05	242	ng/mL		5104620000169	OK
CSD1101	3	5	45	10	4.13	249	ng/mL		5104620000170	OK
CSD1101	3	5	60	11	3.69	253	ng/mL		5104620000171	OK
CSD1101	3	5	75	12	3.65	246	ng/mL		5104620000172	OK
CSD1101	3	5	90	13	3.75	254	ng/mL		5104620000173	OK

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	3	5	120	14	3.95	238	ng/mL		5104620000174	OK
CSD1101	3	5	150	15	3.20	244	ng/mL		5104620000175	OK
CSD1101	3	5	180	16	3.05	248	ng/mL		5104620000176	OK
CSD1101	4	1	Pre-0	1	0.681	122	ng/mL		5104620000305	OK
CSD1101	4	1	0	2	0.602	123	ng/mL		5104620000306	OK
CSD1101	4	1	3	3	30.2	131	ng/mL		5104620000307	OK
CSD1101	4	1	5	4	37.7	123	ng/mL		5104620000308	OK
CSD1101	4	1	7.5	5	21.8	124	ng/mL		5104620000309	OK
CSD1101	4	1	10	6	18.4	127	ng/mL		5104620000310	OK
CSD1101	4	1	15	7	14.0	136	ng/mL		5104620000311	OK
CSD1101	4	1	20	8	10.6	132	ng/mL		5104620000312	OK
CSD1101	4	1	30	9	7.71	130	ng/mL		5104620000313	OK
CSD1101	4	1	45	10	6.54	138	ng/mL		5104620000314	OK
CSD1101	4	1	60	11	5.76	133	ng/mL		5104620000315	OK
CSD1101	4	1	75	12	4.07	120	ng/mL		5104620000316	OK
CSD1101	4	1	90	13	3.64	128	ng/mL		5104620000317	OK
CSD1101	4	1	120	14	2.50	129	ng/mL		5104620000318	OK
CSD1101	4	1	150	15	2.56	129	ng/mL		5104620000319	OK
CSD1101	4	1	180	16	2.40	134	ng/mL		5104620000320	OK
CSD1101	4	2	Pre-0	1	1.12	166	ng/mL		5104620000289	OK
CSD1101	4	2	0	2	0.896	166	ng/mL		5104620000290	OK
CSD1101	4	2	3	3	1.33	164	ng/mL		5104620000291	OK
CSD1101	4	2	5	4	2.07	166	ng/mL		5104620000292	OK
CSD1101	4	2	7.5	5	3.71	154	ng/mL		5104620000293	OK

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	4	2	10	6	4.28	160	ng/mL		5104620000294	OK
CSD1101	4	2	15	7	4.84	158	ng/mL		5104620000295	OK
CSD1101	4	2	20	8	6.51	168	ng/mL		5104620000296	OK
CSD1101	4	2	30	9	7.16	167	ng/mL		5104620000297	OK
CSD1101	4	2	45	10	4.84	178	ng/mL		5104620000298	OK
CSD1101	4	2	60	11	4.34	174	ng/mL		5104620000299	OK
CSD1101	4	2	75	12	3.70	177	ng/mL		5104620000300	OK
CSD1101	4	2	90	13	3.29	162	ng/mL		5104620000301	OK
CSD1101	4	2	120	14	2.64	156	ng/mL		5104620000302	OK
CSD1101	4	2	150	15	2.18	159	ng/mL		5104620000303	OK
CSD1101	4	2	180	16	1.99	163	ng/mL		5104620000304	OK
CSD1101	4	3	Pre-0	1	1.50	165	ng/mL		5104620000273	OK
CSD1101	4	3	0	2	1.45	165	ng/mL		5104620000274	OK
CSD1101	4	3	3	3	1.64	161	ng/mL		5104620000275	OK
CSD1101	4	3	5	4	2.11	153	ng/mL		5104620000276	OK
CSD1101	4	3	7.5	5	2.50	161	ng/mL		5104620000277	OK
CSD1101	4	3	10	6	2.26	161	ng/mL		5104620000278	OK
CSD1101	4	3	15	7	2.83	158	ng/mL		5104620000279	OK
CSD1101	4	3	20	8	3.05	155	ng/mL		5104620000280	OK
CSD1101	4	3	30	9	2.40	156	ng/mL		5104620000281	OK
CSD1101	4	3	45	10	2.15	154	ng/mL		5104620000282	OK
CSD1101	4	3	60	11	2.54	154	ng/mL		5104620000283	OK
CSD1101	4	3	75	12	2.33	150	ng/mL		5104620000284	OK
CSD1101	4	3	90	13	2.25	153	ng/mL		5104620000285	OK

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	4	3	120	14	2.02	148	ng/mL		5104620000286	OK
CSD1101	4	3	150	15	1.75	160	ng/mL		5104620000287	OK
CSD1101	4	3	180	16	1.51	151	ng/mL		5104620000288	OK
CSD1101	4	4	Pre-0	1	BLQ<(0.500)	112	ng/mL		5104620000257	OK
CSD1101	4	4	0	2	BLQ<(0.500)	103	ng/mL		5104620000258	OK
CSD1101	4	4	3	3	1.01	120	ng/mL		5104620000259	OK
CSD1101	4	4	5	4	1.53	100	ng/mL		5104620000260	OK
CSD1101	4	4	7.5	5	2.54	108	ng/mL		5104620000261	OK
CSD1101	4	4	10	6	2.62	111	ng/mL		5104620000262	OK
CSD1101	4	4	15	7	4.71	106	ng/mL		5104620000263	OK
CSD1101	4	4	20	8	4.48	115	ng/mL		5104620000264	OK
CSD1101	4	4	30	9	3.78	109	ng/mL		5104620000265	OK
CSD1101	4	4	45	10	3.60	111	ng/mL		5104620000266	OK
CSD1101	4	4	60	11	2.45	107	ng/mL		5104620000267	OK
CSD1101	4	4	75	12	2.08	106	ng/mL		5104620000268	OK
CSD1101	4	4	90	13	1.72	106	ng/mL		5104620000269	OK
CSD1101	4	4	120	14	1.31	100	ng/mL		5104620000270	OK
CSD1101	4	4	150	15	1.03	103	ng/mL		5104620000271	OK
CSD1101	4	4	180	16	0.891	105	ng/mL		5104620000272	OK
CSD1101	4	5	Pre-0	1	0.686	81.0	ng/mL		5104620000241	OK
CSD1101	4	5	0	2	0.638	79.2	ng/mL		5104620000242	OK
CSD1101	4	5	3	3	0.782	84.2	ng/mL		5104620000243	OK
CSD1101	4	5	5	4	1.64	83.3	ng/mL		5104620000244	OK
CSD1101	4	5	7.5	5	3.34	79.1	ng/mL		5104620000245	OK

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	4	5	10	6	3.55	83.2	ng/mL		5104620000246	OK
CSD1101	4	5	15	7	2.51	84.3	ng/mL		5104620000247	OK
CSD1101	4	5	20	8	3.41	82.4	ng/mL		5104620000248	OK
CSD1101	4	5	30	9	2.42	83.7	ng/mL		5104620000249	OK
CSD1101	4	5	45	10	2.37	88.9	ng/mL		5104620000250	OK
CSD1101	4	5	60	11	1.71	84.5	ng/mL		5104620000251	OK
CSD1101	4	5	75	12	1.52	82.0	ng/mL		5104620000252	OK
CSD1101	4	5	90	13	1.30	83.4	ng/mL		5104620000253	OK
CSD1101	4	5	120	14	0.958	77.8	ng/mL		5104620000254	OK
CSD1101	4	5	150	15	0.993	79.9	ng/mL		5104620000255	OK
CSD1101	4	5	180	16	0.778	78.2	ng/mL		5104620000256	OK
CSD1101	5	1	Pre-0	1	1.20	186	ng/mL		5104620000385	OK
CSD1101	5	1	0	2	1.13	181	ng/mL		5104620000386	OK
CSD1101	5	1	3	3	12.5	193	ng/mL		5104620000387	OK
CSD1101	5	1	5	4	15.5	179	ng/mL		5104620000388	OK
CSD1101	5	1	7.5	5	16.0	180	ng/mL		5104620000389	OK
CSD1101	5	1	10	6	12.2	182	ng/mL		5104620000390	OK
CSD1101	5	1	15	7	10.6	175	ng/mL		5104620000391	OK
CSD1101	5	1	20	8	7.80	185	ng/mL		5104620000392	OK
CSD1101	5	1	30	9	6.70	180	ng/mL		5104620000393	OK
CSD1101	5	1	45	10	6.09	187	ng/mL		5104620000394	OK
CSD1101	5	1	60	11	5.25	182	ng/mL		5104620000395	OK
CSD1101	5	1	75	12	4.78	192	ng/mL		5104620000396	OK
CSD1101	5	1	90	13	4.04	170	ng/mL		5104620000397	OK

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	5	1	120	14	3.64	164	ng/mL		5104620000398	OK
CSD1101	5	1	150	15	3.26	164	ng/mL		5104620000399	OK
CSD1101	5	1	180	16	2.84	165	ng/mL		5104620000400	OK
CSD1101	5	2	Pre-0	1	2.12	218	ng/mL		5104620000369	OK
CSD1101	5	2	0	2	2.16	208	ng/mL		5104620000370	OK
CSD1101	5	2	3	3	1.98	208	ng/mL		5104620000371	OK
CSD1101	5	2	5	4	2.29	212	ng/mL		5104620000372	OK
CSD1101	5	2	7.5	5	3.14	216	ng/mL		5104620000373	OK
CSD1101	5	2	10	6	3.79	259	ng/mL		5104620000374	OK
CSD1101	5	2	15	7	3.59	214	ng/mL		5104620000375	OK
CSD1101	5	2	20	8	3.50	225	ng/mL		5104620000376	OK
CSD1101	5	2	30	9	3.76	222	ng/mL		5104620000377	OK
CSD1101	5	2	45	10	3.19	218	ng/mL		5104620000378	OK
CSD1101	5	2	60	11	2.93	210	ng/mL		5104620000379	OK
CSD1101	5	2	75	12	2.90	206	ng/mL		5104620000380	OK
CSD1101	5	2	90	13	2.64	198	ng/mL		5104620000381	OK
CSD1101	5	2	120	14	2.26	194	ng/mL		5104620000382	OK
CSD1101	5	2	150	15	1.93	187	ng/mL		5104620000383	OK
CSD1101	5	2	180	16	1.77	187	ng/mL		5104620000384	OK
CSD1101	5	3	Pre-0	1	0.843	176	ng/mL		5104620000353	OK
CSD1101	5	3	0	2	0.768	177	ng/mL		5104620000354	OK
CSD1101	5	3	3	3	0.835	171	ng/mL		5104620000355	OK
CSD1101	5	3	5	4	1.37	175	ng/mL		5104620000356	OK
CSD1101	5	3	7.5	5	1.85	161	ng/mL		5104620000357	OK

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	5	3	10	6	2.08	156	ng/mL		5104620000358	OK
CSD1101	5	3	15	7	2.10	164	ng/mL		5104620000359	OK
CSD1101	5	3	20	8	2.23	181	ng/mL		5104620000360	OK
CSD1101	5	3	30	9	2.49	185	ng/mL		5104620000361	OK
CSD1101	5	3	45	10	2.32	181	ng/mL		5104620000362	OK
CSD1101	5	3	60	11	2.52	179	ng/mL		5104620000363	OK
CSD1101	5	3	75	12	2.16	164	ng/mL		5104620000364	OK
CSD1101	5	3	90	13	2.18	170	ng/mL		5104620000365	OK
CSD1101	5	3	120	14	1.83	161	ng/mL		5104620000366	OK
CSD1101	5	3	150	15	1.40	152	ng/mL		5104620000367	OK
CSD1101	5	3	180	16	1.30	153	ng/mL		5104620000368	OK
CSD1101	5	4	Pre-0	1	1.31	193	ng/mL		5104620000337	OK
CSD1101	5	4	0	2	1.27	189	ng/mL		5104620000338	OK
CSD1101	5	4	3	3	1.77	179	ng/mL		5104620000339	OK
CSD1101	5	4	5	4	1.77	195	ng/mL		5104620000340	OK
CSD1101	5	4	7.5	5	2.05	186	ng/mL		5104620000341	OK
CSD1101	5	4	10	6	2.13	186	ng/mL		5104620000342	OK
CSD1101	5	4	15	7	2.20	180	ng/mL		5104620000343	OK
CSD1101	5	4	20	8	2.43	183	ng/mL		5104620000344	OK
CSD1101	5	4	30	9	2.14	182	ng/mL		5104620000345	OK
CSD1101	5	4	45	10	2.43	189	ng/mL		5104620000346	OK
CSD1101	5	4	60	11	2.23	177	ng/mL		5104620000347	OK
CSD1101	5	4	75	12	2.17	176	ng/mL		5104620000348	OK
CSD1101	5	4	90	13	1.73	166	ng/mL		5104620000349	OK

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	5	4	120	14	1.73	171	ng/mL		5104620000350	OK
CSD1101	5	4	150	15	1.54	167	ng/mL		5104620000351	OK
CSD1101	5	4	180	16	1.31	167	ng/mL		5104620000352	OK
CSD1101	5	5	Pre-0	1	1.14	177	ng/mL		5104620000321	OK
CSD1101	5	5	0	2	1.12	173	ng/mL		5104620000322	OK
CSD1101	5	5	3	3	1.11	175	ng/mL		5104620000323	OK
CSD1101	5	5	5	4	1.37	173	ng/mL		5104620000324	OK
CSD1101	5	5	7.5	5	1.81	166	ng/mL		5104620000325	OK
CSD1101	5	5	10	6	1.90	171	ng/mL		5104620000326	OK
CSD1101	5	5	15	7	2.81	175	ng/mL		5104620000327	OK
CSD1101	5	5	20	8	2.74	172	ng/mL		5104620000328	OK
CSD1101	5	5	30	9	2.87	174	ng/mL		5104620000329	OK
CSD1101	5	5	45	10	3.12	173	ng/mL		5104620000330	OK
CSD1101	5	5	60	11	2.97	180	ng/mL		5104620000331	OK
CSD1101	5	5	75	12	2.55	166	ng/mL		5104620000332	OK
CSD1101	5	5	90	13	2.49	168	ng/mL		5104620000333	OK
CSD1101	5	5	120	14	2.52	168	ng/mL		5104620000334	OK
CSD1101	5	5	150	15	2.32	164	ng/mL		5104620000335	OK
CSD1101	5	5	180	16	1.87	161	ng/mL		5104620000336	OK
CSD1101	6	1	Pre-0	1	BLQ<(0.500)	108	ng/mL		5104620000465	OK
CSD1101	6	1	0	2	BLQ<(0.500)	109	ng/mL		5104620000466	OK
CSD1101	6	1	3	3	2.69	108	ng/mL		5104620000467	OK
CSD1101	6	1	5	4	4.19	108	ng/mL		5104620000468	OK
CSD1101	6	1	7.5	5	6.31	95.7	ng/mL		5104620000469	OK

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	6	1	10	6	8.35	112	ng/mL		5104620000470	OK
CSD1101	6	1	15	7	5.57	108	ng/mL		5104620000471	OK
CSD1101	6	1	20	8	5.28	109	ng/mL		5104620000472	OK
CSD1101	6	1	30	9	4.28	109	ng/mL		5104620000473	OK
CSD1101	6	1	45	10	3.95	112	ng/mL		5104620000474	OK
CSD1101	6	1	60	11	3.39	108	ng/mL		5104620000475	OK
CSD1101	6	1	75	12	3.28	109	ng/mL		5104620000476	OK
CSD1101	6	1	90	13	3.33	108	ng/mL		5104620000477	OK
CSD1101	6	1	120	14	2.57	100	ng/mL		5104620000478	OK
CSD1101	6	1	150	15	2.24	97.5	ng/mL		5104620000479	OK
CSD1101	6	1	180	16	1.66	96.2	ng/mL		5104620000480	OK
CSD1101	6	2	Pre-0	1	BLQ<(0.500)	127	ng/mL		5104620000449	OK
CSD1101	6	2	0	2	BLQ<(0.500)	129	ng/mL		5104620000450	OK
CSD1101	6	2	3	3	BLQ<(0.500)	127	ng/mL		5104620000451	OK
CSD1101	6	2	5	4	BLQ<(0.500)	118	ng/mL		5104620000452	OK
CSD1101	6	2	7.5	5	0.757	125	ng/mL		5104620000453	OK
CSD1101	6	2	10	6	1.08	127	ng/mL		5104620000454	OK
CSD1101	6	2	15	7	1.65	124	ng/mL		5104620000455	OK
CSD1101	6	2	20	8	1.56	125	ng/mL		5104620000456	OK
CSD1101	6	2	30	9	1.53	122	ng/mL		5104620000457	OK
CSD1101	6	2	45	10	1.52	122	ng/mL		5104620000458	OK
CSD1101	6	2	60	11	1.34	116	ng/mL		5104620000459	OK
CSD1101	6	2	75	12	1.21	124	ng/mL		5104620000460	OK
CSD1101	6	2	90	13	1.14	118	ng/mL		5104620000461	OK

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	6	2	120	14	1.14	120	ng/mL		5104620000462	OK
CSD1101	6	2	150	15	0.829	124	ng/mL		5104620000463	OK
CSD1101	6	2	180	16	0.763	116	ng/mL		5104620000464	OK
CSD1101	6	3	Pre-0	1	BLQ<(0.500)	94.0	ng/mL		5104620000433	OK
CSD1101	6	3	0	2	BLQ<(0.500)	97.6	ng/mL		5104620000434	OK
CSD1101	6	3	3	3	1.05	93.5	ng/mL		5104620000435	OK
CSD1101	6	3	5	4	1.70	93.3	ng/mL		5104620000436	OK
CSD1101	6	3	7.5	5	2.05	94.9	ng/mL		5104620000437	OK
CSD1101	6	3	10	6	1.74	97.9	ng/mL		5104620000438	OK
CSD1101	6	3	15	7	1.63	90.8	ng/mL		5104620000439	OK
CSD1101	6	3	20	8	1.94	88.5	ng/mL		5104620000440	OK
CSD1101	6	3	30	9	1.88	92.7	ng/mL		5104620000441	OK
CSD1101	6	3	45	10	1.28	93.5	ng/mL		5104620000442	OK
CSD1101	6	3	60	11	1.41	92.6	ng/mL		5104620000443	OK
CSD1101	6	3	75	12	1.12	91.4	ng/mL		5104620000444	OK
CSD1101	6	3	90	13	1.13	89.7	ng/mL		5104620000445	OK
CSD1101	6	3	120	14	1.18	87.7	ng/mL		5104620000446	OK
CSD1101	6	3	150	15	0.872	82.9	ng/mL		5104620000447	OK
CSD1101	6	3	180	16	0.775	83.4	ng/mL		5104620000448	OK
CSD1101	6	4	Pre-0	1	BLQ<(0.500)	93.6	ng/mL		5104620000417	OK
CSD1101	6	4	0	2	BLQ<(0.500)	94.9	ng/mL		5104620000418	OK
CSD1101	6	4	3	3	BLQ<(0.500)	95.0	ng/mL		5104620000419	OK
CSD1101	6	4	5	4	BLQ<(0.500)	92.8	ng/mL		5104620000420	OK
CSD1101	6	4	7.5	5	BLQ<(0.500)	91.6	ng/mL		5104620000421	OK

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	6	4	10	6	0.598	91.3	ng/mL		5104620000422	OK
CSD1101	6	4	15	7	0.779	92.1	ng/mL		5104620000423	OK
CSD1101	6	4	20	8	1.13	89.0	ng/mL		5104620000424	OK
CSD1101	6	4	30	9	1.26	90.0	ng/mL		5104620000425	OK
CSD1101	6	4	45	10	1.01	90.1	ng/mL		5104620000426	OK
CSD1101	6	4	60	11	0.980	93.7	ng/mL		5104620000427	OK
CSD1101	6	4	75	12	1.02	94.2	ng/mL		5104620000428	OK
CSD1101	6	4	90	13	1.00	95.3	ng/mL		5104620000429	OK
CSD1101	6	4	120	14	0.818	90.7	ng/mL		5104620000430	OK
CSD1101	6	4	150	15	0.677	89.0	ng/mL		5104620000431	OK
CSD1101	6	4	180	16	0.570	84.7	ng/mL		5104620000432	OK
CSD1101	6	5	Pre-0	1	BLQ<(0.500)	109	ng/mL		5104620000401	OK
CSD1101	6	5	0	2	BLQ<(0.500)	106	ng/mL		5104620000402	OK
CSD1101	6	5	3	3	BLQ<(0.500)	107	ng/mL		5104620000403	OK
CSD1101	6	5	5	4	BLQ<(0.500)	111	ng/mL		5104620000404	OK
CSD1101	6	5	7.5	5	0.517	107	ng/mL		5104620000405	OK
CSD1101	6	5	10	6	0.562	105	ng/mL		5104620000406	OK
CSD1101	6	5	15	7	0.751	105	ng/mL		5104620000407	OK
CSD1101	6	5	20	8	1.07	106	ng/mL		5104620000408	OK
CSD1101	6	5	30	9	0.943	104	ng/mL		5104620000409	OK
CSD1101	6	5	45	10	1.44	110	ng/mL		5104620000410	OK
CSD1101	6	5	60	11	1.19	111	ng/mL		5104620000411	OK
CSD1101	6	5	75	12	0.860	103	ng/mL		5104620000412	OK
CSD1101	6	5	90	13	0.985	105	ng/mL		5104620000413	OK

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	6	5	120	14	0.721	102	ng/mL		5104620000414	OK
CSD1101	6	5	150	15	0.626	101	ng/mL		5104620000415	OK
CSD1101	6	5	180	16	0.584	97.1	ng/mL		5104620000416	OK
CSD1101	7	1	Pre-0	1	0.911	92.4	ng/mL		5104620000545	OK
CSD1101	7	1	0	2	0.573	91.7	ng/mL		5104620000546	OK
CSD1101	7	1	3	3	3.48	89.6	ng/mL		5104620000547	OK
CSD1101	7	1	5	4	5.65	90.8	ng/mL		5104620000548	OK
CSD1101	7	1	7.5	5	9.31	93.5	ng/mL		5104620000549	OK
CSD1101	7	1	10	6	10.1	95.8	ng/mL		5104620000550	OK
CSD1101	7	1	15	7	9.21	98.2	ng/mL		5104620000551	OK
CSD1101	7	1	20	8	7.51	91.0	ng/mL		5104620000552	OK
CSD1101	7	1	30	9	6.82	99.1	ng/mL		5104620000553	OK
CSD1101	7	1	45	10	5.71	104	ng/mL		5104620000554	OK
CSD1101	7	1	60	11	5.11	101	ng/mL		5104620000555	OK
CSD1101	7	1	75	12	4.72	100	ng/mL		5104620000556	OK
CSD1101	7	1	90	13	4.46	103	ng/mL		5104620000557	OK
CSD1101	7	1	120	14	3.62	94.2	ng/mL		5104620000558	OK
CSD1101	7	1	150	15	3.26	88.2	ng/mL		5104620000559	OK
CSD1101	7	1	180	16	2.32	85.0	ng/mL		5104620000560	OK
CSD1101	7	2	Pre-0	1	.	.	ng/mL	Not Received	5104620000529	Not Received
CSD1101	7	2	0	2	.	.	ng/mL	Not Received	5104620000530	Not Received
CSD1101	7	2	3	3	.	.	ng/mL	Not Received	5104620000531	Not Received
CSD1101	7	2	5	4	.	.	ng/mL	Not Received	5104620000532	Not Received
CSD1101	7	2	7.5	5	.	.	ng/mL	Not Received	5104620000533	Not Received

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	7	2	10	6	.	.	ng/mL	Not Received	5104620000534	Not Received
CSD1101	7	2	15	7	.	.	ng/mL	Not Received	5104620000535	Not Received
CSD1101	7	2	20	8	.	.	ng/mL	Not Received	5104620000536	Not Received
CSD1101	7	2	30	9	.	.	ng/mL	Not Received	5104620000537	Not Received
CSD1101	7	2	45	10	.	.	ng/mL	Not Received	5104620000538	Not Received
CSD1101	7	2	60	11	.	.	ng/mL	Not Received	5104620000539	Not Received
CSD1101	7	2	75	12	.	.	ng/mL	Not Received	5104620000540	Not Received
CSD1101	7	2	90	13	.	.	ng/mL	Not Received	5104620000541	Not Received
CSD1101	7	2	120	14	.	.	ng/mL	Not Received	5104620000542	Not Received
CSD1101	7	2	150	15	.	.	ng/mL	Not Received	5104620000543	Not Received
CSD1101	7	2	180	16	.	.	ng/mL	Not Received	5104620000544	Not Received
CSD1101	7	3	Pre-0	1	.	.	ng/mL	Not Received	5104620000513	Not Received
CSD1101	7	3	0	2	.	.	ng/mL	Not Received	5104620000514	Not Received
CSD1101	7	3	3	3	.	.	ng/mL	Not Received	5104620000515	Not Received
CSD1101	7	3	5	4	.	.	ng/mL	Not Received	5104620000516	Not Received
CSD1101	7	3	7.5	5	.	.	ng/mL	Not Received	5104620000517	Not Received
CSD1101	7	3	10	6	.	.	ng/mL	Not Received	5104620000518	Not Received
CSD1101	7	3	15	7	.	.	ng/mL	Not Received	5104620000519	Not Received
CSD1101	7	3	20	8	.	.	ng/mL	Not Received	5104620000520	Not Received
CSD1101	7	3	30	9	.	.	ng/mL	Not Received	5104620000521	Not Received
CSD1101	7	3	45	10	.	.	ng/mL	Not Received	5104620000522	Not Received
CSD1101	7	3	60	11	.	.	ng/mL	Not Received	5104620000523	Not Received
CSD1101	7	3	75	12	.	.	ng/mL	Not Received	5104620000524	Not Received
CSD1101	7	3	90	13	.	.	ng/mL	Not Received	5104620000525	Not Received

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	7	3	120	14	.	.	ng/mL	Not Received	5104620000526	Not Received
CSD1101	7	3	150	15	.	.	ng/mL	Not Received	5104620000527	Not Received
CSD1101	7	3	180	16	.	.	ng/mL	Not Received	5104620000528	Not Received
CSD1101	7	4	Pre-0	1	.	.	ng/mL	Not Received	5104620000497	Not Received
CSD1101	7	4	0	2	.	.	ng/mL	Not Received	5104620000498	Not Received
CSD1101	7	4	3	3	.	.	ng/mL	Not Received	5104620000499	Not Received
CSD1101	7	4	5	4	.	.	ng/mL	Not Received	5104620000500	Not Received
CSD1101	7	4	7.5	5	.	.	ng/mL	Not Received	5104620000501	Not Received
CSD1101	7	4	10	6	.	.	ng/mL	Not Received	5104620000502	Not Received
CSD1101	7	4	15	7	.	.	ng/mL	Not Received	5104620000503	Not Received
CSD1101	7	4	20	8	.	.	ng/mL	Not Received	5104620000504	Not Received
CSD1101	7	4	30	9	.	.	ng/mL	Not Received	5104620000505	Not Received
CSD1101	7	4	45	10	.	.	ng/mL	Not Received	5104620000506	Not Received
CSD1101	7	4	60	11	.	.	ng/mL	Not Received	5104620000507	Not Received
CSD1101	7	4	75	12	.	.	ng/mL	Not Received	5104620000508	Not Received
CSD1101	7	4	90	13	.	.	ng/mL	Not Received	5104620000509	Not Received
CSD1101	7	4	120	14	.	.	ng/mL	Not Received	5104620000510	Not Received
CSD1101	7	4	150	15	.	.	ng/mL	Not Received	5104620000511	Not Received
CSD1101	7	4	180	16	.	.	ng/mL	Not Received	5104620000512	Not Received
CSD1101	7	5	Pre-0	1	.	.	ng/mL	Not Received	5104620000481	Not Received
CSD1101	7	5	0	2	.	.	ng/mL	Not Received	5104620000482	Not Received
CSD1101	7	5	3	3	.	.	ng/mL	Not Received	5104620000483	Not Received
CSD1101	7	5	5	4	.	.	ng/mL	Not Received	5104620000484	Not Received
CSD1101	7	5	7.5	5	.	.	ng/mL	Not Received	5104620000485	Not Received

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	7	5	10	6	.	.	ng/mL	Not Received	5104620000486	Not Received
CSD1101	7	5	15	7	.	.	ng/mL	Not Received	5104620000487	Not Received
CSD1101	7	5	20	8	.	.	ng/mL	Not Received	5104620000488	Not Received
CSD1101	7	5	30	9	.	.	ng/mL	Not Received	5104620000489	Not Received
CSD1101	7	5	45	10	.	.	ng/mL	Not Received	5104620000490	Not Received
CSD1101	7	5	60	11	.	.	ng/mL	Not Received	5104620000491	Not Received
CSD1101	7	5	75	12	.	.	ng/mL	Not Received	5104620000492	Not Received
CSD1101	7	5	90	13	.	.	ng/mL	Not Received	5104620000493	Not Received
CSD1101	7	5	120	14	.	.	ng/mL	Not Received	5104620000494	Not Received
CSD1101	7	5	150	15	.	.	ng/mL	Not Received	5104620000495	Not Received
CSD1101	7	5	180	16	.	.	ng/mL	Not Received	5104620000496	Not Received
CSD1101	8	1	Pre-0	1	1.05	166	ng/mL		5104620000625	OK
CSD1101	8	1	0	2	1.16	169	ng/mL		5104620000626	OK
CSD1101	8	1	3	3	4.98	167	ng/mL		5104620000627	OK
CSD1101	8	1	5	4	7.99	166	ng/mL		5104620000628	OK
CSD1101	8	1	7.5	5	9.39	165	ng/mL		5104620000629	OK
CSD1101	8	1	10	6	9.76	162	ng/mL		5104620000630	OK
CSD1101	8	1	15	7	9.94	165	ng/mL		5104620000631	OK
CSD1101	8	1	20	8	9.80	167	ng/mL		5104620000632	OK
CSD1101	8	1	30	9	7.86	167	ng/mL		5104620000633	OK
CSD1101	8	1	45	10	6.91	167	ng/mL		5104620000634	OK
CSD1101	8	1	60	11	6.59	167	ng/mL		5104620000635	OK
CSD1101	8	1	75	12	6.08	167	ng/mL		5104620000636	OK
CSD1101	8	1	90	13	5.70	171	ng/mL		5104620000637	OK

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	8	1	120	14	5.20	171	ng/mL		5104620000638	OK
CSD1101	8	1	150	15	4.54	161	ng/mL		5104620000639	OK
CSD1101	8	1	180	16	4.45	161	ng/mL		5104620000640	OK
CSD1101	8	2	Pre-0	1	BLQ<(0.500)	120	ng/mL		5104620000609	OK
CSD1101	8	2	0	2	0.506	126	ng/mL		5104620000610	OK
CSD1101	8	2	3	3	0.593	123	ng/mL		5104620000611	OK
CSD1101	8	2	5	4	0.894	134	ng/mL		5104620000612	OK
CSD1101	8	2	7.5	5	1.22	120	ng/mL		5104620000613	OK
CSD1101	8	2	10	6	1.45	119	ng/mL		5104620000614	OK
CSD1101	8	2	15	7	1.57	121	ng/mL		5104620000615	OK
CSD1101	8	2	20	8	1.73	120	ng/mL		5104620000616	OK
CSD1101	8	2	30	9	1.86	127	ng/mL		5104620000617	OK
CSD1101	8	2	45	10	1.79	124	ng/mL		5104620000618	OK
CSD1101	8	2	60	11	1.55	119	ng/mL		5104620000619	OK
CSD1101	8	2	75	12	1.53	119	ng/mL		5104620000620	OK
CSD1101	8	2	90	13	1.46	118	ng/mL		5104620000621	OK
CSD1101	8	2	120	14	1.23	115	ng/mL		5104620000622	OK
CSD1101	8	2	150	15	1.25	116	ng/mL		5104620000623	OK
CSD1101	8	2	180	16	1.15	118	ng/mL		5104620000624	OK
CSD1101	8	3	Pre-0	1	0.962	120	ng/mL		5104620000593	OK
CSD1101	8	3	0	2	0.948	120	ng/mL		5104620000594	OK
CSD1101	8	3	3	3	0.923	119	ng/mL		5104620000595	OK
CSD1101	8	3	5	4	1.02	127	ng/mL		5104620000596	OK
CSD1101	8	3	7.5	5	.	.	ng/mL	Not Received	5104620000597	Not Received

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	8	3	10	6	1.48	124	ng/mL		5104620000598	OK
CSD1101	8	3	15	7	1.33	133	ng/mL		5104620000599	OK
CSD1101	8	3	20	8	1.53	116	ng/mL		5104620000600	OK
CSD1101	8	3	30	9	1.74	121	ng/mL		5104620000601	OK
CSD1101	8	3	45	10	1.74	119	ng/mL		5104620000602	OK
CSD1101	8	3	60	11	2.07	129	ng/mL		5104620000603	OK
CSD1101	8	3	75	12	2.15	120	ng/mL		5104620000604	OK
CSD1101	8	3	90	13	2.02	127	ng/mL		5104620000605	OK
CSD1101	8	3	120	14	1.81	118	ng/mL		5104620000606	OK
CSD1101	8	3	150	15	1.72	111	ng/mL		5104620000607	OK
CSD1101	8	3	180	16	1.47	107	ng/mL		5104620000608	OK
CSD1101	8	4	Pre-0	1	0.902	140	ng/mL		5104620000577	OK
CSD1101	8	4	0	2	0.925	143	ng/mL		5104620000578	OK
CSD1101	8	4	3	3	0.995	145	ng/mL		5104620000579	OK
CSD1101	8	4	5	4	1.12	154	ng/mL		5104620000580	OK
CSD1101	8	4	7.5	5	0.913	141	ng/mL		5104620000581	OK
CSD1101	8	4	10	6	0.965	138	ng/mL		5104620000582	OK
CSD1101	8	4	15	7	1.18	147	ng/mL		5104620000583	OK
CSD1101	8	4	20	8	1.09	135	ng/mL		5104620000584	OK
CSD1101	8	4	30	9	1.23	138	ng/mL		5104620000585	OK
CSD1101	8	4	45	10	1.52	139	ng/mL		5104620000586	OK
CSD1101	8	4	60	11	2.21	150	ng/mL		5104620000587	OK
CSD1101	8	4	75	12	2.14	142	ng/mL		5104620000588	OK
CSD1101	8	4	90	13	2.02	145	ng/mL		5104620000589	OK

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	8	4	120	14	1.61	134	ng/mL		5104620000590	OK
CSD1101	8	4	150	15	1.75	134	ng/mL		5104620000591	OK
CSD1101	8	4	180	16	1.38	131	ng/mL		5104620000592	OK
CSD1101	8	5	Pre-0	1	0.877	152	ng/mL		5104620000561	OK
CSD1101	8	5	0	2	1.16	171	ng/mL		5104620000562	OK
CSD1101	8	5	3	3	1.15	158	ng/mL		5104620000563	OK
CSD1101	8	5	5	4	0.849	144	ng/mL		5104620000564	OK
CSD1101	8	5	7.5	5	1.02	144	ng/mL		5104620000565	OK
CSD1101	8	5	10	6	1.05	153	ng/mL		5104620000566	OK
CSD1101	8	5	15	7	1.46	149	ng/mL		5104620000567	OK
CSD1101	8	5	20	8	1.69	145	ng/mL		5104620000568	OK
CSD1101	8	5	30	9	1.88	147	ng/mL		5104620000569	OK
CSD1101	8	5	45	10	2.23	147	ng/mL		5104620000570	OK
CSD1101	8	5	60	11	1.92	141	ng/mL		5104620000571	OK
CSD1101	8	5	75	12	1.86	141	ng/mL		5104620000572	OK
CSD1101	8	5	90	13	1.76	137	ng/mL		5104620000573	OK
CSD1101	8	5	120	14	1.61	141	ng/mL		5104620000574	OK
CSD1101	8	5	150	15	1.39	136	ng/mL		5104620000575	OK
CSD1101	8	5	180	16	1.40	132	ng/mL		5104620000576	OK
CSD1101	9	1	Pre-0	1	0.876	216	ng/mL		5104620000705	OK
CSD1101	9	1	0	2	1.15	205	ng/mL		5104620000706	OK
CSD1101	9	1	3	3	7.68	204	ng/mL		5104620000707	OK
CSD1101	9	1	5	4	10.0	206	ng/mL		5104620000708	OK
CSD1101	9	1	7.5	5	12.1	200	ng/mL		5104620000709	OK

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	9	1	10	6	9.78	200	ng/mL		5104620000710	OK
CSD1101	9	1	15	7	9.10	209	ng/mL		5104620000711	OK
CSD1101	9	1	20	8	8.22	199	ng/mL		5104620000712	OK
CSD1101	9	1	30	9	7.92	204	ng/mL		5104620000713	OK
CSD1101	9	1	45	10	6.63	206	ng/mL		5104620000714	OK
CSD1101	9	1	60	11	5.69	202	ng/mL		5104620000715	OK
CSD1101	9	1	75	12	5.32	194	ng/mL		5104620000716	OK
CSD1101	9	1	90	13	4.81	210	ng/mL		5104620000717	OK
CSD1101	9	1	120	14	3.22	188	ng/mL		5104620000718	OK
CSD1101	9	1	150	15	3.15	181	ng/mL		5104620000719	OK
CSD1101	9	1	180	16	2.46	190	ng/mL		5104620000720	OK
CSD1101	9	2	Pre-0	1	1.15	249	ng/mL		5104620000689	OK
CSD1101	9	2	0	2	1.04	248	ng/mL		5104620000690	OK
CSD1101	9	2	3	3	1.23	253	ng/mL		5104620000691	OK
CSD1101	9	2	5	4	1.27	250	ng/mL		5104620000692	OK
CSD1101	9	2	7.5	5	1.69	243	ng/mL		5104620000693	OK
CSD1101	9	2	10	6	1.58	244	ng/mL		5104620000694	OK
CSD1101	9	2	15	7	2.11	240	ng/mL		5104620000695	OK
CSD1101	9	2	20	8	1.81	249	ng/mL		5104620000696	OK
CSD1101	9	2	30	9	3.40	243	ng/mL		5104620000697	OK
CSD1101	9	2	45	10	3.65	233	ng/mL		5104620000698	OK
CSD1101	9	2	60	11	3.56	247	ng/mL		5104620000699	OK
CSD1101	9	2	75	12	2.75	237	ng/mL		5104620000700	OK
CSD1101	9	2	90	13	2.81	242	ng/mL		5104620000701	OK

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	9	2	120	14	2.57	231	ng/mL		5104620000702	OK
CSD1101	9	2	150	15	2.16	232	ng/mL		5104620000703	OK
CSD1101	9	2	180	16	1.89	219	ng/mL		5104620000704	OK
CSD1101	9	3	Pre-0	1	1.17	210	ng/mL		5104620000673	OK
CSD1101	9	3	0	2	1.12	215	ng/mL		5104620000674	OK
CSD1101	9	3	3	3	1.36	211	ng/mL		5104620000675	OK
CSD1101	9	3	5	4	1.20	209	ng/mL		5104620000676	OK
CSD1101	9	3	7.5	5	1.79	209	ng/mL		5104620000677	OK
CSD1101	9	3	10	6	2.07	213	ng/mL		5104620000678	OK
CSD1101	9	3	15	7	1.79	207	ng/mL		5104620000679	OK
CSD1101	9	3	20	8	2.92	219	ng/mL		5104620000680	OK
CSD1101	9	3	30	9	2.59	208	ng/mL		5104620000681	OK
CSD1101	9	3	45	10	3.12	204	ng/mL		5104620000682	OK
CSD1101	9	3	60	11	2.94	203	ng/mL		5104620000683	OK
CSD1101	9	3	75	12	2.52	197	ng/mL		5104620000684	OK
CSD1101	9	3	90	13	2.24	197	ng/mL		5104620000685	OK
CSD1101	9	3	120	14	2.15	197	ng/mL		5104620000686	OK
CSD1101	9	3	150	15	2.10	191	ng/mL		5104620000687	OK
CSD1101	9	3	180	16	1.81	185	ng/mL		5104620000688	OK
CSD1101	9	4	Pre-0	1	1.11	211	ng/mL		5104620000657	OK
CSD1101	9	4	0	2	0.733	207	ng/mL		5104620000658	OK
CSD1101	9	4	3	3	2.77	198	ng/mL		5104620000659	OK
CSD1101	9	4	5	4	1.98	210	ng/mL		5104620000660	OK
CSD1101	9	4	7.5	5	2.58	204	ng/mL		5104620000661	OK

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	9	4	10	6	2.66	199	ng/mL		5104620000662	OK
CSD1101	9	4	15	7	4.12	202	ng/mL		5104620000663	OK
CSD1101	9	4	20	8	3.42	203	ng/mL		5104620000664	OK
CSD1101	9	4	30	9	2.95	207	ng/mL		5104620000665	OK
CSD1101	9	4	45	10	2.62	199	ng/mL		5104620000666	OK
CSD1101	9	4	60	11	2.23	194	ng/mL		5104620000667	OK
CSD1101	9	4	75	12	2.03	195	ng/mL		5104620000668	OK
CSD1101	9	4	90	13	1.94	196	ng/mL		5104620000669	OK
CSD1101	9	4	120	14	1.91	189	ng/mL		5104620000670	OK
CSD1101	9	4	150	15	1.36	183	ng/mL		5104620000671	OK
CSD1101	9	4	180	16	1.29	174	ng/mL		5104620000672	OK
CSD1101	9	5	Pre-0	1	0.962	245	ng/mL		5104620000641	OK
CSD1101	9	5	0	2	1.01	241	ng/mL		5104620000642	OK
CSD1101	9	5	3	3	0.966	239	ng/mL		5104620000643	OK
CSD1101	9	5	5	4	1.02	232	ng/mL		5104620000644	OK
CSD1101	9	5	7.5	5	1.47	231	ng/mL		5104620000645	OK
CSD1101	9	5	10	6	1.81	230	ng/mL		5104620000646	OK
CSD1101	9	5	15	7	2.45	233	ng/mL		5104620000647	OK
CSD1101	9	5	20	8	2.26	233	ng/mL		5104620000648	OK
CSD1101	9	5	30	9	2.12	243	ng/mL		5104620000649	OK
CSD1101	9	5	45	10	2.91	235	ng/mL		5104620000650	OK
CSD1101	9	5	60	11	2.75	230	ng/mL		5104620000651	OK
CSD1101	9	5	75	12	2.61	237	ng/mL		5104620000652	OK
CSD1101	9	5	90	13	2.50	224	ng/mL		5104620000653	OK

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	9	5	120	14	2.29	222	ng/mL		5104620000654	OK
CSD1101	9	5	150	15	1.99	221	ng/mL		5104620000655	OK
CSD1101	9	5	180	16	1.72	218	ng/mL		5104620000656	OK
CSD1101	10	1	Pre-0	1	0.981	215	ng/mL		5104620000785	OK
CSD1101	10	1	0	2	0.837	228	ng/mL		5104620000786	OK
CSD1101	10	1	3	3	2.65	214	ng/mL		5104620000787	OK
CSD1101	10	1	5	4	3.44	214	ng/mL		5104620000788	OK
CSD1101	10	1	7.5	5	7.18	256	ng/mL		5104620000789	OK
CSD1101	10	1	10	6	7.16	218	ng/mL		5104620000790	OK
CSD1101	10	1	15	7	7.08	216	ng/mL		5104620000791	OK
CSD1101	10	1	20	8	7.54	215	ng/mL		5104620000792	OK
CSD1101	10	1	30	9	7.26	214	ng/mL		5104620000793	OK
CSD1101	10	1	45	10	6.08	219	ng/mL		5104620000794	OK
CSD1101	10	1	60	11	4.87	214	ng/mL		5104620000795	OK
CSD1101	10	1	75	12	3.92	212	ng/mL		5104620000796	OK
CSD1101	10	1	90	13	3.76	223	ng/mL		5104620000797	OK
CSD1101	10	1	120	14	3.46	211	ng/mL		5104620000798	OK
CSD1101	10	1	150	15	2.69	207	ng/mL		5104620000799	OK
CSD1101	10	1	180	16	2.29	201	ng/mL		5104620000800	OK
CSD1101	10	2	Pre-0	1	1.92	253	ng/mL		5104620000769	OK
CSD1101	10	2	0	2	2.19	248	ng/mL		5104620000770	OK
CSD1101	10	2	3	3	1.99	251	ng/mL		5104620000771	OK
CSD1101	10	2	5	4	2.28	263	ng/mL		5104620000772	OK
CSD1101	10	2	7.5	5	2.69	248	ng/mL		5104620000773	OK

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	10	2	10	6	3.04	244	ng/mL		5104620000774	OK
CSD1101	10	2	15	7	4.72	247	ng/mL		5104620000775	OK
CSD1101	10	2	20	8	5.34	247	ng/mL		5104620000776	OK
CSD1101	10	2	30	9	5.35	245	ng/mL		5104620000777	OK
CSD1101	10	2	45	10	6.77	258	ng/mL		5104620000778	OK
CSD1101	10	2	60	11	7.43	257	ng/mL		5104620000779	OK
CSD1101	10	2	75	12	6.49	257	ng/mL		5104620000780	OK
CSD1101	10	2	90	13	5.87	268	ng/mL		5104620000781	OK
CSD1101	10	2	120	14	4.49	266	ng/mL		5104620000782	OK
CSD1101	10	2	150	15	3.42	262	ng/mL		5104620000783	OK
CSD1101	10	2	180	16	3.67	256	ng/mL		5104620000784	OK
CSD1101	10	3	Pre-0	1	3.07	343	ng/mL		5104620000753	OK
CSD1101	10	3	0	2	3.76	329	ng/mL		5104620000754	OK
CSD1101	10	3	3	3	3.09	341	ng/mL		5104620000755	OK
CSD1101	10	3	5	4	3.31	341	ng/mL		5104620000756	OK
CSD1101	10	3	7.5	5	3.23	334	ng/mL		5104620000757	OK
CSD1101	10	3	10	6	3.49	334	ng/mL		5104620000758	OK
CSD1101	10	3	15	7	3.84	331	ng/mL		5104620000759	OK
CSD1101	10	3	20	8	3.99	327	ng/mL		5104620000760	OK
CSD1101	10	3	30	9	3.74	328	ng/mL		5104620000761	OK
CSD1101	10	3	45	10	4.87	338	ng/mL		5104620000762	OK
CSD1101	10	3	60	11	5.28	337	ng/mL		5104620000763	OK
CSD1101	10	3	75	12	5.32	332	ng/mL		5104620000764	OK
CSD1101	10	3	90	13	4.67	332	ng/mL		5104620000765	OK

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	10	3	120	14	4.08	325	ng/mL		5104620000766	OK
CSD1101	10	3	150	15	3.67	307	ng/mL		5104620000767	OK
CSD1101	10	3	180	16	3.03	318	ng/mL		5104620000768	OK
CSD1101	10	4	Pre-0	1	1.79	250	ng/mL		5104620000737	OK
CSD1101	10	4	0	2	1.65	258	ng/mL		5104620000738	OK
CSD1101	10	4	3	3	1.77	247	ng/mL		5104620000739	OK
CSD1101	10	4	5	4	1.88	258	ng/mL		5104620000740	OK
CSD1101	10	4	7.5	5	2.20	256	ng/mL		5104620000741	OK
CSD1101	10	4	10	6	2.51	270	ng/mL		5104620000742	OK
CSD1101	10	4	15	7	2.49	253	ng/mL		5104620000743	OK
CSD1101	10	4	20	8	3.30	256	ng/mL		5104620000744	OK
CSD1101	10	4	30	9	3.75	249	ng/mL		5104620000745	OK
CSD1101	10	4	45	10	4.16	256	ng/mL		5104620000746	OK
CSD1101	10	4	60	11	3.83	261	ng/mL		5104620000747	OK
CSD1101	10	4	75	12	3.43	258	ng/mL		5104620000748	OK
CSD1101	10	4	90	13	3.10	257	ng/mL		5104620000749	OK
CSD1101	10	4	120	14	2.60	255	ng/mL		5104620000750	OK
CSD1101	10	4	150	15	2.16	250	ng/mL		5104620000751	OK
CSD1101	10	4	180	16	1.84	249	ng/mL		5104620000752	OK
CSD1101	10	5	Pre-0	1	1.23	317	ng/mL		5104620000721	OK
CSD1101	10	5	0	2	1.28	314	ng/mL		5104620000722	OK
CSD1101	10	5	3	3	1.26	316	ng/mL		5104620000723	OK
CSD1101	10	5	5	4	1.42	315	ng/mL		5104620000724	OK
CSD1101	10	5	7.5	5	1.62	318	ng/mL		5104620000725	OK

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	10	5	10	6	2.00	304	ng/mL		5104620000726	OK
CSD1101	10	5	15	7	2.47	313	ng/mL		5104620000727	OK
CSD1101	10	5	20	8	3.70	309	ng/mL		5104620000728	OK
CSD1101	10	5	30	9	4.93	316	ng/mL		5104620000729	OK
CSD1101	10	5	45	10	3.88	309	ng/mL		5104620000730	OK
CSD1101	10	5	60	11	3.36	311	ng/mL		5104620000731	OK
CSD1101	10	5	75	12	2.88	312	ng/mL		5104620000732	OK
CSD1101	10	5	90	13	2.54	307	ng/mL		5104620000733	OK
CSD1101	10	5	120	14	2.01	267	ng/mL		5104620000734	OK
CSD1101	10	5	150	15	1.62	298	ng/mL		5104620000735	OK
CSD1101	10	5	180	16	1.65	278	ng/mL		5104620000736	OK
CSD1101	11	1	Pre-0	1	0.958	253	ng/mL		5104620000865	OK
CSD1101	11	1	0	2	0.992	249	ng/mL		5104620000866	OK
CSD1101	11	1	3	3	19.0	254	ng/mL		5104620000867	OK
CSD1101	11	1	5	4	30.9	241	ng/mL		5104620000868	OK
CSD1101	11	1	7.5	5	19.6	254	ng/mL		5104620000869	OK
CSD1101	11	1	10	6	14.6	251	ng/mL		5104620000870	OK
CSD1101	11	1	15	7	11.6	252	ng/mL		5104620000871	OK
CSD1101	11	1	20	8	9.01	259	ng/mL		5104620000872	OK
CSD1101	11	1	30	9	7.52	261	ng/mL		5104620000873	OK
CSD1101	11	1	45	10	5.28	253	ng/mL		5104620000874	OK
CSD1101	11	1	60	11	4.31	251	ng/mL		5104620000875	OK
CSD1101	11	1	75	12	4.79	255	ng/mL		5104620000876	OK
CSD1101	11	1	90	13	3.86	245	ng/mL		5104620000877	OK

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	11	1	120	14	3.40	246	ng/mL		5104620000878	OK
CSD1101	11	1	150	15	2.48	240	ng/mL		5104620000879	OK
CSD1101	11	1	180	16	2.45	232	ng/mL		5104620000880	OK
CSD1101	11	2	Pre-0	1	0.711	170	ng/mL		5104620000849	OK
CSD1101	11	2	0	2	0.616	151	ng/mL		5104620000850	OK
CSD1101	11	2	3	3	0.613	151	ng/mL		5104620000851	OK
CSD1101	11	2	5	4	0.660	148	ng/mL		5104620000852	OK
CSD1101	11	2	7.5	5	0.695	148	ng/mL		5104620000853	OK
CSD1101	11	2	10	6	0.857	155	ng/mL		5104620000854	OK
CSD1101	11	2	15	7	0.844	154	ng/mL		5104620000855	OK
CSD1101	11	2	20	8	0.957	154	ng/mL		5104620000856	OK
CSD1101	11	2	30	9	1.26	164	ng/mL		5104620000857	OK
CSD1101	11	2	45	10	1.52	148	ng/mL		5104620000858	OK
CSD1101	11	2	60	11	1.76	153	ng/mL		5104620000859	OK
CSD1101	11	2	75	12	1.58	153	ng/mL		5104620000860	OK
CSD1101	11	2	90	13	1.90	175	ng/mL		5104620000861	OK
CSD1101	11	2	120	14	1.35	152	ng/mL		5104620000862	OK
CSD1101	11	2	150	15	1.15	148	ng/mL		5104620000863	OK
CSD1101	11	2	180	16	1.04	145	ng/mL		5104620000864	OK
CSD1101	11	3	Pre-0	1	0.801	184	ng/mL		5104620000833	OK
CSD1101	11	3	0	2	0.868	182	ng/mL		5104620000834	OK
CSD1101	11	3	3	3	1.20	183	ng/mL		5104620000835	OK
CSD1101	11	3	5	4	1.65	185	ng/mL		5104620000836	OK
CSD1101	11	3	7.5	5	1.59	182	ng/mL		5104620000837	OK

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	11	3	10	6	1.67	182	ng/mL		5104620000838	OK
CSD1101	11	3	15	7	1.96	184	ng/mL		5104620000839	OK
CSD1101	11	3	20	8	2.14	183	ng/mL		5104620000840	OK
CSD1101	11	3	30	9	1.87	185	ng/mL		5104620000841	OK
CSD1101	11	3	45	10	1.73	186	ng/mL		5104620000842	OK
CSD1101	11	3	60	11	1.49	188	ng/mL		5104620000843	OK
CSD1101	11	3	75	12	1.47	189	ng/mL		5104620000844	OK
CSD1101	11	3	90	13	1.46	184	ng/mL		5104620000845	OK
CSD1101	11	3	120	14	1.22	183	ng/mL		5104620000846	OK
CSD1101	11	3	150	15	1.16	182	ng/mL		5104620000847	OK
CSD1101	11	3	180	16	1.01	174	ng/mL		5104620000848	OK
CSD1101	11	4	Pre-0	1	0.887	224	ng/mL		5104620000817	OK
CSD1101	11	4	0	2	0.932	226	ng/mL		5104620000818	OK
CSD1101	11	4	3	3	0.925	224	ng/mL		5104620000819	OK
CSD1101	11	4	5	4	1.01	225	ng/mL		5104620000820	OK
CSD1101	11	4	7.5	5	1.25	224	ng/mL		5104620000821	OK
CSD1101	11	4	10	6	1.47	229	ng/mL		5104620000822	OK
CSD1101	11	4	15	7	1.75	229	ng/mL		5104620000823	OK
CSD1101	11	4	20	8	1.73	226	ng/mL		5104620000824	OK
CSD1101	11	4	30	9	1.70	223	ng/mL		5104620000825	OK
CSD1101	11	4	45	10	2.35	230	ng/mL		5104620000826	OK
CSD1101	11	4	60	11	1.89	234	ng/mL		5104620000827	OK
CSD1101	11	4	75	12	1.89	229	ng/mL		5104620000828	OK
CSD1101	11	4	90	13	1.81	226	ng/mL		5104620000829	OK

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	11	4	120	14	1.49	228	ng/mL		5104620000830	OK
CSD1101	11	4	150	15	1.30	220	ng/mL		5104620000831	OK
CSD1101	11	4	180	16	1.25	227	ng/mL		5104620000832	OK
CSD1101	11	5	Pre-0	1	0.756	190	ng/mL		5104620000801	OK
CSD1101	11	5	0	2	0.703	186	ng/mL		5104620000802	OK
CSD1101	11	5	3	3	0.753	190	ng/mL		5104620000803	OK
CSD1101	11	5	5	4	0.900	192	ng/mL		5104620000804	OK
CSD1101	11	5	7.5	5	0.822	189	ng/mL		5104620000805	OK
CSD1101	11	5	10	6	1.07	188	ng/mL		5104620000806	OK
CSD1101	11	5	15	7	1.26	184	ng/mL		5104620000807	OK
CSD1101	11	5	20	8	1.48	185	ng/mL		5104620000808	OK
CSD1101	11	5	30	9	1.51	182	ng/mL		5104620000809	OK
CSD1101	11	5	45	10	1.32	182	ng/mL		5104620000810	OK
CSD1101	11	5	60	11	1.90	183	ng/mL		5104620000811	OK
CSD1101	11	5	75	12	2.00	185	ng/mL		5104620000812	OK
CSD1101	11	5	90	13	1.92	187	ng/mL		5104620000813	OK
CSD1101	11	5	120	14	1.47	187	ng/mL		5104620000814	OK
CSD1101	11	5	150	15	1.29	182	ng/mL		5104620000815	OK
CSD1101	11	5	180	16	1.06	180	ng/mL		5104620000816	OK
CSD1101	12	1	Pre-0	1	4.62	529	ng/mL		5104620000945	OK
CSD1101	12	1	0	2	5.01	547	ng/mL		5104620000946	OK
CSD1101	12	1	3	3	37.6	543	ng/mL		5104620000947	OK
CSD1101	12	1	5	4	39.3	534	ng/mL		5104620000948	OK
CSD1101	12	1	7.5	5	35.2	541	ng/mL		5104620000949	OK

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	12	1	10	6	33.7	539	ng/mL		5104620000950	OK
CSD1101	12	1	15	7	29.8	532	ng/mL		5104620000951	OK
CSD1101	12	1	20	8	25.9	561	ng/mL		5104620000952	OK
CSD1101	12	1	30	9	21.1	551	ng/mL		5104620000953	OK
CSD1101	12	1	45	10	18.2	545	ng/mL		5104620000954	OK
CSD1101	12	1	60	11	14.9	532	ng/mL		5104620000955	OK
CSD1101	12	1	75	12	12.8	522	ng/mL		5104620000956	OK
CSD1101	12	1	90	13	11.3	522	ng/mL		5104620000957	OK
CSD1101	12	1	120	14	8.94	511	ng/mL		5104620000958	OK
CSD1101	12	1	150	15	8.21	519	ng/mL		5104620000959	OK
CSD1101	12	1	180	16	7.75	522	ng/mL		5104620000960	OK
CSD1101	12	2	Pre-0	1	4.19	438	ng/mL		5104620000929	OK
CSD1101	12	2	0	2	3.79	435	ng/mL		5104620000930	OK
CSD1101	12	2	3	3	3.08	419	ng/mL		5104620000931	OK
CSD1101	12	2	5	4	3.40	417	ng/mL		5104620000932	OK
CSD1101	12	2	7.5	5	3.98	429	ng/mL		5104620000933	OK
CSD1101	12	2	10	6	4.49	432	ng/mL		5104620000934	OK
CSD1101	12	2	15	7	4.86	429	ng/mL		5104620000935	OK
CSD1101	12	2	20	8	5.06	423	ng/mL		5104620000936	OK
CSD1101	12	2	30	9	5.09	427	ng/mL		5104620000937	OK
CSD1101	12	2	45	10	5.66	440	ng/mL		5104620000938	OK
CSD1101	12	2	60	11	4.16	419	ng/mL		5104620000939	OK
CSD1101	12	2	75	12	3.75	411	ng/mL		5104620000940	OK
CSD1101	12	2	90	13	4.17	417	ng/mL		5104620000941	OK

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	12	2	120	14	4.16	408	ng/mL		5104620000942	OK
CSD1101	12	2	150	15	2.86	407	ng/mL		5104620000943	OK
CSD1101	12	2	180	16	2.63	414	ng/mL		5104620000944	OK
CSD1101	12	3	Pre-0	1	6.55	415	ng/mL		5104620000913	OK
CSD1101	12	3	0	2	6.91	422	ng/mL		5104620000914	OK
CSD1101	12	3	3	3	6.87	435	ng/mL		5104620000915	OK
CSD1101	12	3	5	4	7.01	423	ng/mL		5104620000916	OK
CSD1101	12	3	7.5	5	8.08	422	ng/mL		5104620000917	OK
CSD1101	12	3	10	6	8.11	418	ng/mL		5104620000918	OK
CSD1101	12	3	15	7	8.25	424	ng/mL		5104620000919	OK
CSD1101	12	3	20	8	8.72	435	ng/mL		5104620000920	OK
CSD1101	12	3	30	9	7.43	421	ng/mL		5104620000921	OK
CSD1101	12	3	45	10	7.25	421	ng/mL		5104620000922	OK
CSD1101	12	3	60	11	7.66	454	ng/mL		5104620000923	OK
CSD1101	12	3	75	12	6.33	420	ng/mL		5104620000924	OK
CSD1101	12	3	90	13	6.92	412	ng/mL		5104620000925	OK
CSD1101	12	3	120	14	5.41	426	ng/mL		5104620000926	OK
CSD1101	12	3	150	15	4.80	431	ng/mL		5104620000927	OK
CSD1101	12	3	180	16	4.11	422	ng/mL		5104620000928	OK
CSD1101	12	4	Pre-0	1	11.9	630	ng/mL		5104620000897	OK
CSD1101	12	4	0	2	12.2	631	ng/mL		5104620000898	OK
CSD1101	12	4	3	3	11.2	634	ng/mL		5104620000899	OK
CSD1101	12	4	5	4	10.7	612	ng/mL		5104620000900	OK
CSD1101	12	4	7.5	5	11.7	691	ng/mL		5104620000901	OK

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	12	4	10	6	11.2	605	ng/mL		5104620000902	OK
CSD1101	12	4	15	7	11.7	621	ng/mL		5104620000903	OK
CSD1101	12	4	20	8	11.4	603	ng/mL		5104620000904	OK
CSD1101	12	4	30	9	10.5	603	ng/mL		5104620000905	OK
CSD1101	12	4	45	10	10.9	600	ng/mL		5104620000906	OK
CSD1101	12	4	60	11	9.53	573	ng/mL		5104620000907	OK
CSD1101	12	4	75	12	8.62	587	ng/mL		5104620000908	OK
CSD1101	12	4	90	13	7.81	584	ng/mL		5104620000909	OK
CSD1101	12	4	120	14	6.36	569	ng/mL		5104620000910	OK
CSD1101	12	4	150	15	5.81	564	ng/mL		5104620000911	OK
CSD1101	12	4	180	16	4.98	566	ng/mL		5104620000912	OK
CSD1101	12	5	Pre-0	1	16.1	722	ng/mL		5104620000881	OK
CSD1101	12	5	0	2	17.5	698	ng/mL		5104620000882	OK
CSD1101	12	5	3	3	16.7	727	ng/mL		5104620000883	OK
CSD1101	12	5	5	4	16.2	725	ng/mL		5104620000884	OK
CSD1101	12	5	7.5	5	16.4	654	ng/mL		5104620000885	OK
CSD1101	12	5	10	6	17.6	738	ng/mL		5104620000886	OK
CSD1101	12	5	15	7	17.8	714	ng/mL		5104620000887	OK
CSD1101	12	5	20	8	18.1	714	ng/mL		5104620000888	OK
CSD1101	12	5	30	9	18.5	809	ng/mL		5104620000889	OK
CSD1101	12	5	45	10	19.2	726	ng/mL		5104620000890	OK
CSD1101	12	5	60	11	16.9	711	ng/mL		5104620000891	OK
CSD1101	12	5	75	12	16.8	717	ng/mL		5104620000892	OK
CSD1101	12	5	90	13	13.0	684	ng/mL		5104620000893	OK

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	12	5	120	14	12.0	710	ng/mL		5104620000894	OK
CSD1101	12	5	150	15	9.27	679	ng/mL		5104620000895	OK
CSD1101	12	5	180	16	9.23	682	ng/mL		5104620000896	OK
CSD1101	13	1	Pre-0	1	0.555	69.6	ng/mL		5104620001025	OK
CSD1101	13	1	0	2	0.659	68.2	ng/mL		5104620001026	OK
CSD1101	13	1	3	3	4.20	72.3	ng/mL		5104620001027	OK
CSD1101	13	1	5	4	5.08	70.9	ng/mL		5104620001028	OK
CSD1101	13	1	7.5	5	5.88	70.8	ng/mL		5104620001029	OK
CSD1101	13	1	10	6	.	.	ng/mL	Non-reportable (ISV)	5104620001030	Other
CSD1101	13	1	15	7	7.14	72.1	ng/mL		5104620001031	OK
CSD1101	13	1	20	8	7.11	77.3	ng/mL		5104620001032	OK
CSD1101	13	1	30	9	6.50	84.6	ng/mL		5104620001033	OK
CSD1101	13	1	45	10	4.25	79.7	ng/mL		5104620001034	OK
CSD1101	13	1	60	11	3.76	82.5	ng/mL		5104620001035	OK
CSD1101	13	1	75	12	3.12	76.4	ng/mL		5104620001036	OK
CSD1101	13	1	90	13	2.55	76.7	ng/mL		5104620001037	OK
CSD1101	13	1	120	14	2.15	79.1	ng/mL		5104620001038	OK
CSD1101	13	1	150	15	2.02	73.5	ng/mL		5104620001039	OK
CSD1101	13	1	180	16	1.57	70.3	ng/mL		5104620001040	OK
CSD1101	13	2	Pre-0	1	1.04	192	ng/mL		5104620001009	OK
CSD1101	13	2	0	2	0.963	190	ng/mL		5104620001010	OK
CSD1101	13	2	3	3	1.04	185	ng/mL		5104620001011	OK
CSD1101	13	2	5	4	1.04	194	ng/mL		5104620001012	OK
CSD1101	13	2	7.5	5	1.33	198	ng/mL		5104620001013	OK

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	13	2	10	6	1.47	192	ng/mL		5104620001014	OK
CSD1101	13	2	15	7	1.53	188	ng/mL		5104620001015	OK
CSD1101	13	2	20	8	1.70	198	ng/mL		5104620001016	OK
CSD1101	13	2	30	9	2.32	195	ng/mL		5104620001017	OK
CSD1101	13	2	45	10	2.52	194	ng/mL		5104620001018	OK
CSD1101	13	2	60	11	1.91	194	ng/mL		5104620001019	OK
CSD1101	13	2	75	12	1.96	190	ng/mL		5104620001020	OK
CSD1101	13	2	90	13	1.63	185	ng/mL		5104620001021	OK
CSD1101	13	2	120	14	1.57	179	ng/mL		5104620001022	OK
CSD1101	13	2	150	15	1.28	173	ng/mL		5104620001023	OK
CSD1101	13	2	180	16	1.32	163	ng/mL		5104620001024	OK
CSD1101	13	3	Pre-0	1	0.871	96.0	ng/mL		5104620000993	OK
CSD1101	13	3	0	2	0.734	104	ng/mL		5104620000994	OK
CSD1101	13	3	3	3	0.934	101	ng/mL		5104620000995	OK
CSD1101	13	3	5	4	2.14	102	ng/mL		5104620000996	OK
CSD1101	13	3	7.5	5	3.16	97.1	ng/mL		5104620000997	OK
CSD1101	13	3	10	6	3.34	95.3	ng/mL		5104620000998	OK
CSD1101	13	3	15	7	3.55	101	ng/mL		5104620000999	OK
CSD1101	13	3	20	8	3.82	102	ng/mL		5104620001000	OK
CSD1101	13	3	30	9	4.08	112	ng/mL		5104620001001	OK
CSD1101	13	3	45	10	3.43	115	ng/mL		5104620001002	OK
CSD1101	13	3	60	11	2.68	113	ng/mL		5104620001003	OK
CSD1101	13	3	75	12	2.56	111	ng/mL		5104620001004	OK
CSD1101	13	3	90	13	2.12	108	ng/mL		5104620001005	OK

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	13	3	120	14	1.88	101	ng/mL		5104620001006	OK
CSD1101	13	3	150	15	1.77	102	ng/mL		5104620001007	OK
CSD1101	13	3	180	16	1.41	95.3	ng/mL		5104620001008	OK
CSD1101	13	4	Pre-0	1	BLQ<(0.500)	108	ng/mL		5104620000977	OK
CSD1101	13	4	0	2	0.541	95.3	ng/mL		5104620000978	OK
CSD1101	13	4	3	3	0.693	114	ng/mL		5104620000979	OK
CSD1101	13	4	5	4	0.713	115	ng/mL		5104620000980	OK
CSD1101	13	4	7.5	5	0.785	112	ng/mL		5104620000981	OK
CSD1101	13	4	10	6	0.830	115	ng/mL		5104620000982	OK
CSD1101	13	4	15	7	1.72	113	ng/mL		5104620000983	OK
CSD1101	13	4	20	8	0.913	103	ng/mL		5104620000984	OK
CSD1101	13	4	30	9	1.26	111	ng/mL		5104620000985	OK
CSD1101	13	4	45	10	1.26	111	ng/mL		5104620000986	OK
CSD1101	13	4	60	11	1.12	106	ng/mL		5104620000987	OK
CSD1101	13	4	75	12	0.923	112	ng/mL		5104620000988	OK
CSD1101	13	4	90	13	0.991	111	ng/mL		5104620000989	OK
CSD1101	13	4	120	14	0.780	98.2	ng/mL		5104620000990	OK
CSD1101	13	4	150	15	0.796	98.3	ng/mL		5104620000991	OK
CSD1101	13	4	180	16	0.874	96.0	ng/mL		5104620000992	OK
CSD1101	13	5	Pre-0	1	0.963	164	ng/mL		5104620000961	OK
CSD1101	13	5	0	2	0.842	173	ng/mL		5104620000962	OK
CSD1101	13	5	3	3	0.925	168	ng/mL		5104620000963	OK
CSD1101	13	5	5	4	0.976	168	ng/mL		5104620000964	OK
CSD1101	13	5	7.5	5	1.11	167	ng/mL		5104620000965	OK

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	13	5	10	6	1.40	163	ng/mL		5104620000966	OK
CSD1101	13	5	15	7	1.63	171	ng/mL		5104620000967	OK
CSD1101	13	5	20	8	2.04	172	ng/mL		5104620000968	OK
CSD1101	13	5	30	9	1.98	169	ng/mL		5104620000969	OK
CSD1101	13	5	45	10	2.05	167	ng/mL		5104620000970	OK
CSD1101	13	5	60	11	1.67	177	ng/mL		5104620000971	OK
CSD1101	13	5	75	12	1.73	168	ng/mL		5104620000972	OK
CSD1101	13	5	90	13	1.54	161	ng/mL		5104620000973	OK
CSD1101	13	5	120	14	1.27	155	ng/mL		5104620000974	OK
CSD1101	13	5	150	15	1.29	153	ng/mL		5104620000975	OK
CSD1101	13	5	180	16	1.09	151	ng/mL		5104620000976	OK
CSD1101	14	1	Pre-0	1	1.07	265	ng/mL		5104620001105	OK
CSD1101	14	1	0	2	0.884	247	ng/mL		5104620001106	OK
CSD1101	14	1	3	3	3.46	250	ng/mL		5104620001107	OK
CSD1101	14	1	5	4	6.14	251	ng/mL		5104620001108	OK
CSD1101	14	1	7.5	5	7.94	272	ng/mL		5104620001109	OK
CSD1101	14	1	10	6	10.5	270	ng/mL		5104620001110	OK
CSD1101	14	1	15	7	9.75	271	ng/mL		5104620001111	OK
CSD1101	14	1	20	8	9.75	274	ng/mL		5104620001112	OK
CSD1101	14	1	30	9	9.83	272	ng/mL		5104620001113	OK
CSD1101	14	1	45	10	8.81	272	ng/mL		5104620001114	OK
CSD1101	14	1	60	11	8.10	272	ng/mL		5104620001115	OK
CSD1101	14	1	75	12	7.51	268	ng/mL		5104620001116	OK
CSD1101	14	1	90	13	6.51	269	ng/mL		5104620001117	OK

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	14	1	120	14	5.05	276	ng/mL		5104620001118	OK
CSD1101	14	1	150	15	4.91	254	ng/mL		5104620001119	OK
CSD1101	14	1	180	16	4.24	251	ng/mL		5104620001120	OK
CSD1101	14	2	Pre-0	1	0.757	253	ng/mL		5104620001089	OK
CSD1101	14	2	0	2	0.754	254	ng/mL		5104620001090	OK
CSD1101	14	2	3	3	0.984	244	ng/mL		5104620001091	OK
CSD1101	14	2	5	4	1.46	243	ng/mL		5104620001092	OK
CSD1101	14	2	7.5	5	1.81	245	ng/mL		5104620001093	OK
CSD1101	14	2	10	6	2.21	242	ng/mL		5104620001094	OK
CSD1101	14	2	15	7	3.06	250	ng/mL		5104620001095	OK
CSD1101	14	2	20	8	3.04	246	ng/mL		5104620001096	OK
CSD1101	14	2	30	9	3.41	244	ng/mL		5104620001097	OK
CSD1101	14	2	45	10	3.73	241	ng/mL		5104620001098	OK
CSD1101	14	2	60	11	3.08	245	ng/mL		5104620001099	OK
CSD1101	14	2	75	12	.	.	ng/mL	Not Received	5104620001100	Not Received
CSD1101	14	2	90	13	2.77	244	ng/mL		5104620001101	OK
CSD1101	14	2	120	14	2.54	234	ng/mL		5104620001102	OK
CSD1101	14	2	150	15	1.96	223	ng/mL		5104620001103	OK
CSD1101	14	2	180	16	1.86	216	ng/mL		5104620001104	OK
CSD1101	14	3	Pre-0	1	0.856	283	ng/mL		5104620001073	OK
CSD1101	14	3	0	2	0.924	280	ng/mL		5104620001074	OK
CSD1101	14	3	3	3	0.903	274	ng/mL		5104620001075	OK
CSD1101	14	3	5	4	1.46	280	ng/mL		5104620001076	OK
CSD1101	14	3	7.5	5	2.02	254	ng/mL		5104620001077	OK

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	14	3	10	6	2.59	278	ng/mL		5104620001078	OK
CSD1101	14	3	15	7	2.74	263	ng/mL		5104620001079	OK
CSD1101	14	3	20	8	2.80	273	ng/mL		5104620001080	OK
CSD1101	14	3	30	9	3.49	261	ng/mL		5104620001081	OK
CSD1101	14	3	45	10	2.64	286	ng/mL		5104620001082	OK
CSD1101	14	3	60	11	2.50	277	ng/mL		5104620001083	OK
CSD1101	14	3	75	12	2.41	269	ng/mL		5104620001084	OK
CSD1101	14	3	90	13	2.05	263	ng/mL		5104620001085	OK
CSD1101	14	3	120	14	1.60	255	ng/mL		5104620001086	OK
CSD1101	14	3	150	15	1.52	241	ng/mL		5104620001087	OK
CSD1101	14	3	180	16	1.24	237	ng/mL		5104620001088	OK
CSD1101	14	4	Pre-0	1	0.695	204	ng/mL		5104620001057	OK
CSD1101	14	4	0	2	0.558	195	ng/mL		5104620001058	OK
CSD1101	14	4	3	3	1.19	198	ng/mL		5104620001059	OK
CSD1101	14	4	5	4	2.26	206	ng/mL		5104620001060	OK
CSD1101	14	4	7.5	5	1.81	191	ng/mL		5104620001061	OK
CSD1101	14	4	10	6	1.85	199	ng/mL		5104620001062	OK
CSD1101	14	4	15	7	2.32	194	ng/mL		5104620001063	OK
CSD1101	14	4	20	8	2.29	204	ng/mL		5104620001064	OK
CSD1101	14	4	30	9	2.19	200	ng/mL		5104620001065	OK
CSD1101	14	4	45	10	2.42	209	ng/mL		5104620001066	OK
CSD1101	14	4	60	11	1.97	193	ng/mL		5104620001067	OK
CSD1101	14	4	75	12	1.83	198	ng/mL		5104620001068	OK
CSD1101	14	4	90	13	1.63	199	ng/mL		5104620001069	OK

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	14	4	120	14	1.76	196	ng/mL		5104620001070	OK
CSD1101	14	4	150	15	1.57	192	ng/mL		5104620001071	OK
CSD1101	14	4	180	16	1.46	185	ng/mL		5104620001072	OK
CSD1101	14	5	Pre-0	1	0.809	221	ng/mL		5104620001041	OK
CSD1101	14	5	0	2	0.671	227	ng/mL		5104620001042	OK
CSD1101	14	5	3	3	0.686	223	ng/mL		5104620001043	OK
CSD1101	14	5	5	4	0.750	215	ng/mL		5104620001044	OK
CSD1101	14	5	7.5	5	0.940	225	ng/mL		5104620001045	OK
CSD1101	14	5	10	6	1.35	220	ng/mL		5104620001046	OK
CSD1101	14	5	15	7	1.55	229	ng/mL		5104620001047	OK
CSD1101	14	5	20	8	1.70	216	ng/mL		5104620001048	OK
CSD1101	14	5	30	9	2.16	209	ng/mL		5104620001049	OK
CSD1101	14	5	45	10	2.78	225	ng/mL		5104620001050	OK
CSD1101	14	5	60	11	2.55	221	ng/mL		5104620001051	OK
CSD1101	14	5	75	12	2.47	217	ng/mL		5104620001052	OK
CSD1101	14	5	90	13	2.38	223	ng/mL		5104620001053	OK
CSD1101	14	5	120	14	2.20	218	ng/mL		5104620001054	OK
CSD1101	14	5	150	15	2.04	212	ng/mL		5104620001055	OK
CSD1101	14	5	180	16	1.71	206	ng/mL		5104620001056	OK
CSD1101	15	1	Pre-0	1	0.955	203	ng/mL		5104620001185	OK
CSD1101	15	1	0	2	0.746	193	ng/mL		5104620001186	OK
CSD1101	15	1	3	3	9.34	194	ng/mL		5104620001187	OK
CSD1101	15	1	5	4	11.3	196	ng/mL		5104620001188	OK
CSD1101	15	1	7.5	5	13.5	212	ng/mL		5104620001189	OK

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	15	1	10	6	18.0	202	ng/mL		5104620001190	OK
CSD1101	15	1	15	7	13.8	207	ng/mL		5104620001191	OK
CSD1101	15	1	20	8	12.7	209	ng/mL		5104620001192	OK
CSD1101	15	1	30	9	10.4	212	ng/mL		5104620001193	OK
CSD1101	15	1	45	10	8.97	214	ng/mL		5104620001194	OK
CSD1101	15	1	60	11	8.15	212	ng/mL		5104620001195	OK
CSD1101	15	1	75	12	6.73	211	ng/mL		5104620001196	OK
CSD1101	15	1	90	13	6.68	212	ng/mL		5104620001197	OK
CSD1101	15	1	120	14	6.13	209	ng/mL		5104620001198	OK
CSD1101	15	1	150	15	4.93	206	ng/mL		5104620001199	OK
CSD1101	15	1	180	16	4.77	213	ng/mL		5104620001200	OK
CSD1101	15	2	Pre-0	1	3.92	260	ng/mL		5104620001169	OK
CSD1101	15	2	0	2	3.52	264	ng/mL		5104620001170	OK
CSD1101	15	2	3	3	4.45	260	ng/mL		5104620001171	OK
CSD1101	15	2	5	4	5.92	260	ng/mL		5104620001172	OK
CSD1101	15	2	7.5	5	6.35	261	ng/mL		5104620001173	OK
CSD1101	15	2	10	6	6.72	265	ng/mL		5104620001174	OK
CSD1101	15	2	15	7	7.43	271	ng/mL		5104620001175	OK
CSD1101	15	2	20	8	6.71	264	ng/mL		5104620001176	OK
CSD1101	15	2	30	9	8.03	264	ng/mL		5104620001177	OK
CSD1101	15	2	45	10	8.18	266	ng/mL		5104620001178	OK
CSD1101	15	2	60	11	6.68	266	ng/mL		5104620001179	OK
CSD1101	15	2	75	12	6.18	254	ng/mL		5104620001180	OK
CSD1101	15	2	90	13	5.74	255	ng/mL		5104620001181	OK

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	15	2	120	14	5.03	252	ng/mL		5104620001182	OK
CSD1101	15	2	150	15	4.79	241	ng/mL		5104620001183	OK
CSD1101	15	2	180	16	4.18	241	ng/mL		5104620001184	OK
CSD1101	15	3	Pre-0	1	1.24	188	ng/mL		5104620001153	OK
CSD1101	15	3	0	2	1.33	188	ng/mL		5104620001154	OK
CSD1101	15	3	3	3	1.26	199	ng/mL		5104620001155	OK
CSD1101	15	3	5	4	1.34	182	ng/mL		5104620001156	OK
CSD1101	15	3	7.5	5	1.61	179	ng/mL		5104620001157	OK
CSD1101	15	3	10	6	1.99	187	ng/mL		5104620001158	OK
CSD1101	15	3	15	7	2.92	183	ng/mL		5104620001159	OK
CSD1101	15	3	20	8	2.80	199	ng/mL		5104620001160	OK
CSD1101	15	3	30	9	3.58	185	ng/mL		5104620001161	OK
CSD1101	15	3	45	10	3.70	195	ng/mL		5104620001162	OK
CSD1101	15	3	60	11	3.13	186	ng/mL		5104620001163	OK
CSD1101	15	3	75	12	2.69	182	ng/mL		5104620001164	OK
CSD1101	15	3	90	13	2.66	180	ng/mL		5104620001165	OK
CSD1101	15	3	120	14	2.69	182	ng/mL		5104620001166	OK
CSD1101	15	3	150	15	2.45	176	ng/mL		5104620001167	OK
CSD1101	15	3	180	16	2.21	172	ng/mL		5104620001168	OK
CSD1101	15	4	Pre-0	1	1.01	200	ng/mL		5104620001137	OK
CSD1101	15	4	0	2	1.00	192	ng/mL		5104620001138	OK
CSD1101	15	4	3	3	0.946	192	ng/mL		5104620001139	OK
CSD1101	15	4	5	4	0.898	182	ng/mL		5104620001140	OK
CSD1101	15	4	7.5	5	1.22	176	ng/mL		5104620001141	OK

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	15	4	10	6	1.58	192	ng/mL		5104620001142	OK
CSD1101	15	4	15	7	2.03	187	ng/mL		5104620001143	OK
CSD1101	15	4	20	8	2.23	179	ng/mL		5104620001144	OK
CSD1101	15	4	30	9	2.89	180	ng/mL		5104620001145	OK
CSD1101	15	4	45	10	3.56	176	ng/mL		5104620001146	OK
CSD1101	15	4	60	11	3.13	201	ng/mL		5104620001147	OK
CSD1101	15	4	75	12	3.81	189	ng/mL		5104620001148	OK
CSD1101	15	4	90	13	3.30	177	ng/mL		5104620001149	OK
CSD1101	15	4	120	14	2.69	175	ng/mL		5104620001150	OK
CSD1101	15	4	150	15	2.52	167	ng/mL		5104620001151	OK
CSD1101	15	4	180	16	2.45	165	ng/mL		5104620001152	OK
CSD1101	15	5	Pre-0	1	3.95	194	ng/mL		5104620001121	OK
CSD1101	15	5	0	2	3.67	199	ng/mL		5104620001122	OK
CSD1101	15	5	3	3	2.84	189	ng/mL		5104620001123	OK
CSD1101	15	5	5	4	2.89	207	ng/mL		5104620001124	OK
CSD1101	15	5	7.5	5	2.71	199	ng/mL		5104620001125	OK
CSD1101	15	5	10	6	3.11	192	ng/mL		5104620001126	OK
CSD1101	15	5	15	7	3.78	207	ng/mL		5104620001127	OK
CSD1101	15	5	20	8	5.60	208	ng/mL		5104620001128	OK
CSD1101	15	5	30	9	7.05	191	ng/mL		5104620001129	OK
CSD1101	15	5	45	10	6.49	209	ng/mL		5104620001130	OK
CSD1101	15	5	60	11	6.71	211	ng/mL		5104620001131	OK
CSD1101	15	5	75	12	5.33	214	ng/mL		5104620001132	OK
CSD1101	15	5	90	13	5.36	194	ng/mL		5104620001133	OK

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	15	5	120	14	4.33	209	ng/mL		5104620001134	OK
CSD1101	15	5	150	15	4.12	189	ng/mL		5104620001135	OK
CSD1101	15	5	180	16	3.74	199	ng/mL		5104620001136	OK
CSD1101	16	1	Pre-0	1	1.16	163	ng/mL		5104620001265	OK
CSD1101	16	1	0	2	1.25	175	ng/mL		5104620001266	OK
CSD1101	16	1	3	3	15.2	177	ng/mL		5104620001267	OK
CSD1101	16	1	5	4	22.6	178	ng/mL		5104620001268	OK
CSD1101	16	1	7.5	5	18.6	182	ng/mL		5104620001269	OK
CSD1101	16	1	10	6	14.2	183	ng/mL		5104620001270	OK
CSD1101	16	1	15	7	11.6	178	ng/mL		5104620001271	OK
CSD1101	16	1	20	8	11.2	174	ng/mL		5104620001272	OK
CSD1101	16	1	30	9	8.32	179	ng/mL		5104620001273	OK
CSD1101	16	1	45	10	7.17	180	ng/mL		5104620001274	OK
CSD1101	16	1	60	11	6.79	191	ng/mL		5104620001275	OK
CSD1101	16	1	75	12	5.72	187	ng/mL		5104620001276	OK
CSD1101	16	1	90	13	5.76	178	ng/mL		5104620001277	OK
CSD1101	16	1	120	14	4.55	176	ng/mL		5104620001278	OK
CSD1101	16	1	150	15	4.53	187	ng/mL		5104620001279	OK
CSD1101	16	1	180	16	2.90	170	ng/mL		5104620001280	OK
CSD1101	16	2	Pre-0	1	1.39	181	ng/mL		5104620001249	OK
CSD1101	16	2	0	2	1.52	181	ng/mL		5104620001250	OK
CSD1101	16	2	3	3	1.49	179	ng/mL		5104620001251	OK
CSD1101	16	2	5	4	2.22	180	ng/mL		5104620001252	OK
CSD1101	16	2	7.5	5	3.12	179	ng/mL		5104620001253	OK

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	16	2	10	6	3.75	179	ng/mL		5104620001254	OK
CSD1101	16	2	15	7	4.12	183	ng/mL		5104620001255	OK
CSD1101	16	2	20	8	4.16	183	ng/mL		5104620001256	OK
CSD1101	16	2	30	9	3.84	182	ng/mL		5104620001257	OK
CSD1101	16	2	45	10	4.13	184	ng/mL		5104620001258	OK
CSD1101	16	2	60	11	3.26	177	ng/mL		5104620001259	OK
CSD1101	16	2	75	12	2.78	182	ng/mL		5104620001260	OK
CSD1101	16	2	90	13	2.84	165	ng/mL		5104620001261	OK
CSD1101	16	2	120	14	2.65	169	ng/mL		5104620001262	OK
CSD1101	16	2	150	15	2.30	173	ng/mL		5104620001263	OK
CSD1101	16	2	180	16	2.12	164	ng/mL		5104620001264	OK
CSD1101	16	3	Pre-0	1	1.24	162	ng/mL		5104620001233	OK
CSD1101	16	3	0	2	1.17	164	ng/mL		5104620001234	OK
CSD1101	16	3	3	3	1.20	162	ng/mL		5104620001235	OK
CSD1101	16	3	5	4	1.71	158	ng/mL		5104620001236	OK
CSD1101	16	3	7.5	5	2.75	158	ng/mL		5104620001237	OK
CSD1101	16	3	10	6	3.16	161	ng/mL		5104620001238	OK
CSD1101	16	3	15	7	3.67	167	ng/mL		5104620001239	OK
CSD1101	16	3	20	8	4.34	170	ng/mL		5104620001240	OK
CSD1101	16	3	30	9	4.74	173	ng/mL		5104620001241	OK
CSD1101	16	3	45	10	3.90	168	ng/mL		5104620001242	OK
CSD1101	16	3	60	11	3.17	160	ng/mL		5104620001243	OK
CSD1101	16	3	75	12	2.70	148	ng/mL		5104620001244	OK
CSD1101	16	3	90	13	2.55	155	ng/mL		5104620001245	OK

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	16	3	120	14	2.28	151	ng/mL		5104620001246	OK
CSD1101	16	3	150	15	2.02	142	ng/mL		5104620001247	OK
CSD1101	16	3	180	16	1.82	147	ng/mL		5104620001248	OK
CSD1101	16	4	Pre-0	1	1.61	181	ng/mL		5104620001217	OK
CSD1101	16	4	0	2	1.59	177	ng/mL		5104620001218	OK
CSD1101	16	4	3	3	1.50	180	ng/mL		5104620001219	OK
CSD1101	16	4	5	4	2.03	179	ng/mL		5104620001220	OK
CSD1101	16	4	7.5	5	2.79	175	ng/mL		5104620001221	OK
CSD1101	16	4	10	6	3.21	180	ng/mL		5104620001222	OK
CSD1101	16	4	15	7	3.41	185	ng/mL		5104620001223	OK
CSD1101	16	4	20	8	3.24	186	ng/mL		5104620001224	OK
CSD1101	16	4	30	9	3.86	198	ng/mL		5104620001225	OK
CSD1101	16	4	45	10	3.62	185	ng/mL		5104620001226	OK
CSD1101	16	4	60	11	3.67	180	ng/mL		5104620001227	OK
CSD1101	16	4	75	12	3.29	176	ng/mL		5104620001228	OK
CSD1101	16	4	90	13	3.12	175	ng/mL		5104620001229	OK
CSD1101	16	4	120	14	2.67	167	ng/mL		5104620001230	OK
CSD1101	16	4	150	15	2.35	164	ng/mL		5104620001231	OK
CSD1101	16	4	180	16	1.86	162	ng/mL		5104620001232	OK
CSD1101	16	5	Pre-0	1	1.81	214	ng/mL		5104620001201	OK
CSD1101	16	5	0	2	1.74	212	ng/mL		5104620001202	OK
CSD1101	16	5	3	3	1.79	213	ng/mL		5104620001203	OK
CSD1101	16	5	5	4	2.27	212	ng/mL		5104620001204	OK
CSD1101	16	5	7.5	5	2.68	206	ng/mL		5104620001205	OK

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	16	5	10	6	3.19	204	ng/mL		5104620001206	OK
CSD1101	16	5	15	7	4.20	202	ng/mL		5104620001207	OK
CSD1101	16	5	20	8	5.00	197	ng/mL		5104620001208	OK
CSD1101	16	5	30	9	7.15	210	ng/mL		5104620001209	OK
CSD1101	16	5	45	10	10.6	227	ng/mL		5104620001210	OK
CSD1101	16	5	60	11	8.45	224	ng/mL		5104620001211	OK
CSD1101	16	5	75	12	7.23	219	ng/mL		5104620001212	OK
CSD1101	16	5	90	13	5.70	208	ng/mL		5104620001213	OK
CSD1101	16	5	120	14	5.94	217	ng/mL		5104620001214	OK
CSD1101	16	5	150	15	5.18	216	ng/mL		5104620001215	OK
CSD1101	16	5	180	16	3.55	175	ng/mL		5104620001216	OK
CSD1101	17	1	Pre-0	1	1.29	204	ng/mL		5104620001345	OK
CSD1101	17	1	0	2	1.54	219	ng/mL		5104620001346	OK
CSD1101	17	1	3	3	13.5	211	ng/mL		5104620001347	OK
CSD1101	17	1	5	4	10.1	214	ng/mL		5104620001348	OK
CSD1101	17	1	7.5	5	12.0	213	ng/mL		5104620001349	OK
CSD1101	17	1	10	6	15.7	220	ng/mL		5104620001350	OK
CSD1101	17	1	15	7	11.3	215	ng/mL		5104620001351	OK
CSD1101	17	1	20	8	10.7	229	ng/mL		5104620001352	OK
CSD1101	17	1	30	9	9.33	222	ng/mL		5104620001353	OK
CSD1101	17	1	45	10	6.30	236	ng/mL		5104620001354	OK
CSD1101	17	1	60	11	5.52	218	ng/mL		5104620001355	OK
CSD1101	17	1	75	12	4.88	206	ng/mL		5104620001356	OK
CSD1101	17	1	90	13	4.07	209	ng/mL		5104620001357	OK

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	17	1	120	14	3.66	209	ng/mL		5104620001358	OK
CSD1101	17	1	150	15	2.77	206	ng/mL		5104620001359	OK
CSD1101	17	1	180	16	2.56	205	ng/mL		5104620001360	OK
CSD1101	17	2	Pre-0	1	2.68	171	ng/mL		5104620001329	OK
CSD1101	17	2	0	2	2.38	168	ng/mL		5104620001330	OK
CSD1101	17	2	3	3	2.44	169	ng/mL		5104620001331	OK
CSD1101	17	2	5	4	2.34	164	ng/mL		5104620001332	OK
CSD1101	17	2	7.5	5	2.52	158	ng/mL		5104620001333	OK
CSD1101	17	2	10	6	2.56	159	ng/mL		5104620001334	OK
CSD1101	17	2	15	7	2.62	158	ng/mL		5104620001335	OK
CSD1101	17	2	20	8	2.49	157	ng/mL		5104620001336	OK
CSD1101	17	2	30	9	2.94	162	ng/mL		5104620001337	OK
CSD1101	17	2	45	10	3.09	165	ng/mL		5104620001338	OK
CSD1101	17	2	60	11	2.76	162	ng/mL		5104620001339	OK
CSD1101	17	2	75	12	2.50	162	ng/mL		5104620001340	OK
CSD1101	17	2	90	13	2.40	160	ng/mL		5104620001341	OK
CSD1101	17	2	120	14	1.87	156	ng/mL		5104620001342	OK
CSD1101	17	2	150	15	1.45	150	ng/mL		5104620001343	OK
CSD1101	17	2	180	16	1.40	153	ng/mL		5104620001344	OK
CSD1101	17	3	Pre-0	1	0.784	236	ng/mL		5104620001313	OK
CSD1101	17	3	0	2	0.747	237	ng/mL		5104620001314	OK
CSD1101	17	3	3	3	0.880	243	ng/mL		5104620001315	OK
CSD1101	17	3	5	4	0.920	226	ng/mL		5104620001316	OK
CSD1101	17	3	7.5	5	1.92	235	ng/mL		5104620001317	OK

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	17	3	10	6	2.22	230	ng/mL		5104620001318	OK
CSD1101	17	3	15	7	2.85	236	ng/mL		5104620001319	OK
CSD1101	17	3	20	8	3.17	215	ng/mL		5104620001320	OK
CSD1101	17	3	30	9	3.17	241	ng/mL		5104620001321	OK
CSD1101	17	3	45	10	2.71	240	ng/mL		5104620001322	OK
CSD1101	17	3	60	11	2.21	244	ng/mL		5104620001323	OK
CSD1101	17	3	75	12	1.59	226	ng/mL		5104620001324	OK
CSD1101	17	3	90	13	1.32	225	ng/mL		5104620001325	OK
CSD1101	17	3	120	14	1.57	221	ng/mL		5104620001326	OK
CSD1101	17	3	150	15	1.56	213	ng/mL		5104620001327	OK
CSD1101	17	3	180	16	1.19	216	ng/mL		5104620001328	OK
CSD1101	17	4	Pre-0	1	1.22	242	ng/mL		5104620001297	OK
CSD1101	17	4	0	2	1.15	262	ng/mL		5104620001298	OK
CSD1101	17	4	3	3	1.21	269	ng/mL		5104620001299	OK
CSD1101	17	4	5	4	1.70	261	ng/mL		5104620001300	OK
CSD1101	17	4	7.5	5	2.03	258	ng/mL		5104620001301	OK
CSD1101	17	4	10	6	2.12	274	ng/mL		5104620001302	OK
CSD1101	17	4	15	7	2.42	258	ng/mL		5104620001303	OK
CSD1101	17	4	20	8	2.84	258	ng/mL		5104620001304	OK
CSD1101	17	4	30	9	3.35	258	ng/mL		5104620001305	OK
CSD1101	17	4	45	10	2.83	250	ng/mL		5104620001306	OK
CSD1101	17	4	60	11	2.44	245	ng/mL		5104620001307	OK
CSD1101	17	4	75	12	2.06	237	ng/mL		5104620001308	OK
CSD1101	17	4	90	13	1.96	238	ng/mL		5104620001309	OK

Protocol	Subject	Visit	Minute Nominal	Time Text	Nicotine Concentration	Cotinine Concentration	Concentration Units	Sample Comments	Custom ID	Sample Condition
CSD1101	17	4	120	14	1.74	242	ng/mL		5104620001310	OK
CSD1101	17	4	150	15	1.53	230	ng/mL		5104620001311	OK
CSD1101	17	4	180	16	1.35	217	ng/mL		5104620001312	OK
CSD1101	17	5	Pre-0	1	0.890	222	ng/mL		5104620001281	OK
CSD1101	17	5	0	2	0.991	230	ng/mL		5104620001282	OK
CSD1101	17	5	3	3	0.789	244	ng/mL		5104620001283	OK
CSD1101	17	5	5	4	0.814	228	ng/mL		5104620001284	OK
CSD1101	17	5	7.5	5	1.04	226	ng/mL		5104620001285	OK
CSD1101	17	5	10	6	1.12	224	ng/mL		5104620001286	OK
CSD1101	17	5	15	7	1.50	222	ng/mL		5104620001287	OK
CSD1101	17	5	20	8	3.03	222	ng/mL		5104620001288	OK
CSD1101	17	5	30	9	4.59	238	ng/mL		5104620001289	OK
CSD1101	17	5	45	10	3.51	229	ng/mL		5104620001290	OK
CSD1101	17	5	60	11	3.04	235	ng/mL		5104620001291	OK
CSD1101	17	5	75	12	2.29	213	ng/mL		5104620001292	OK
CSD1101	17	5	90	13	2.01	217	ng/mL		5104620001293	OK
CSD1101	17	5	120	14	1.68	224	ng/mL		5104620001294	OK
CSD1101	17	5	150	15	1.49	214	ng/mL		5104620001295	OK
CSD1101	17	5	180	16	1.60	226	ng/mL		5104620001296	OK

Table 6. Summary of Reassays for Analytical Reasons

Analyte	Batch Number	Reason	Sample Name
Nicotine	4	UISR	AA97220-01 05104620000314 04 N/A 10 / Day 1 0.75h SER-1
Nicotine	10	LSR	AA97220-01 05104620000705 09 N/A 1 / Day 1 -0.0333h SER-1
Nicotine	10	LSR	AA97220-01 05104620000658 09 N/A 2 / Day 1 0h SER-1
Nicotine	11	Fail	AA97220-01 05104620000641 09 N/A 1 / Day 1 -0.0333h SER-1
Nicotine	11	Fail	AA97220-01 05104620000642 09 N/A 2 / Day 1 0h SER-1
Nicotine	11	Fail	AA97220-01 05104620000643 09 N/A 3 / Day 1 0.05h SER-1
Nicotine	11	Fail	AA97220-01 05104620000644 09 N/A 4 / Day 1 0.0833h SER-1
Nicotine	11	Fail	AA97220-01 05104620000645 09 N/A 5 / Day 1 0.125h SER-1
Nicotine	11	Fail	AA97220-01 05104620000646 09 N/A 6 / Day 1 0.1667h SER-1
Nicotine	11	Fail	AA97220-01 05104620000647 09 N/A 7 / Day 1 0.25h SER-1
Nicotine	11	Fail	AA97220-01 05104620000648 09 N/A 8 / Day 1 0.333h SER-1
Nicotine	11	Fail	AA97220-01 05104620000649 09 N/A 9 / Day 1 0.5h SER-1
Nicotine	11	Fail	AA97220-01 05104620000650 09 N/A 10 / Day 1 0.75h SER-1
Nicotine	11	Fail	AA97220-01 05104620000651 09 N/A 11 / Day 1 1h SER-1
Nicotine	11	Fail	AA97220-01 05104620000652 09 N/A 12 / Day 1 1.25h SER-1
Nicotine	11	Fail	AA97220-01 05104620000653 09 N/A 13 / Day 1 1.5h SER-1
Nicotine	11	Fail	AA97220-01 05104620000654 09 N/A 14 / Day 1 2h SER-1
Nicotine	11	Fail	AA97220-01 05104620000655 09 N/A 15 / Day 1 2.5h SER-1
Nicotine	11	Fail	AA97220-01 05104620000656 09 N/A 16 / Day 1 3h SER-1
Nicotine	11	Fail	AA97220-01 05104620000785 10 N/A 1 / Day 1 -0.0333h SER-1
Nicotine	11	Fail	AA97220-01 05104620000753 10 N/A 1 / Day 1 -0.0333h SER-1
Nicotine	11	Fail	AA97220-01 05104620000769 10 N/A 1 / Day 1 -0.0333h SER-1
Nicotine	11	Fail	AA97220-01 05104620000770 10 N/A 2 / Day 1 0h SER-1
Nicotine	11	Fail	AA97220-01 05104620000754 10 N/A 2 / Day 1 0h SER-1
Nicotine	11	Fail	AA97220-01 05104620000786 10 N/A 2 / Day 1 0h SER-1
Nicotine	11	Fail	AA97220-01 05104620000755 10 N/A 3 / Day 1 0.05h SER-1
Nicotine	11	Fail	AA97220-01 05104620000771 10 N/A 3 / Day 1 0.05h SER-1
Nicotine	11	Fail	AA97220-01 05104620000787 10 N/A 3 / Day 1 0.05h SER-1
Nicotine	11	Fail	AA97220-01 05104620000772 10 N/A 4 / Day 1 0.0833h SER-1
Nicotine	11	Fail	AA97220-01 05104620000756 10 N/A 4 / Day 1 0.0833h SER-1
Nicotine	11	Fail	AA97220-01 05104620000788 10 N/A 4 / Day 1 0.0833h SER-1
Nicotine	11	Fail	AA97220-01 05104620000773 10 N/A 5 / Day 1 0.125h SER-1
Nicotine	11	Fail	AA97220-01 05104620000789 10 N/A 5 / Day 1 0.125h SER-1
Nicotine	11	Fail	AA97220-01 05104620000757 10 N/A 5 / Day 1 0.125h SER-1
Nicotine	11	Fail	AA97220-01 05104620000790 10 N/A 6 / Day 1 0.1667h SER-1
Nicotine	11	Fail	AA97220-01 05104620000758 10 N/A 6 / Day 1 0.1667h SER-1
Nicotine	11	Fail	AA97220-01 05104620000774 10 N/A 6 / Day 1 0.1667h SER-1
Nicotine	11	Fail	AA97220-01 05104620000759 10 N/A 7 / Day 1 0.25h SER-1
Nicotine	11	Fail	AA97220-01 05104620000775 10 N/A 7 / Day 1 0.25h SER-1

Analyte	Batch Number	Reason	Sample Name
Nicotine	11	Fail	AA97220-01 05104620000791 10 N/A 7 / Day 1 0.25h SER-1
Nicotine	11	Fail	AA97220-01 05104620000760 10 N/A 8 / Day 1 0.333h SER-1
Nicotine	11	Fail	AA97220-01 05104620000776 10 N/A 8 / Day 1 0.333h SER-1
Nicotine	11	Fail	AA97220-01 05104620000792 10 N/A 8 / Day 1 0.333h SER-1
Nicotine	11	Fail	AA97220-01 05104620000793 10 N/A 9 / Day 1 0.5h SER-1
Nicotine	11	Fail	AA97220-01 05104620000761 10 N/A 9 / Day 1 0.5h SER-1
Nicotine	11	Fail	AA97220-01 05104620000777 10 N/A 9 / Day 1 0.5h SER-1
Nicotine	11	Fail	AA97220-01 05104620000762 10 N/A 10 / Day 1 0.75h SER-1
Nicotine	11	Fail	AA97220-01 05104620000794 10 N/A 10 / Day 1 0.75h SER-1
Nicotine	11	Fail	AA97220-01 05104620000778 10 N/A 10 / Day 1 0.75h SER-1
Nicotine	11	Fail	AA97220-01 05104620000795 10 N/A 11 / Day 1 1h SER-1
Nicotine	11	Fail	AA97220-01 05104620000763 10 N/A 11 / Day 1 1h SER-1
Nicotine	11	Fail	AA97220-01 05104620000779 10 N/A 11 / Day 1 1h SER-1
Nicotine	11	Fail	AA97220-01 05104620000780 10 N/A 12 / Day 1 1.25h SER-1
Nicotine	11	Fail	AA97220-01 05104620000796 10 N/A 12 / Day 1 1.25h SER-1
Nicotine	11	Fail	AA97220-01 05104620000764 10 N/A 12 / Day 1 1.25h SER-1
Nicotine	11	Fail	AA97220-01 05104620000781 10 N/A 13 / Day 1 1.5h SER-1
Nicotine	11	Fail	AA97220-01 05104620000797 10 N/A 13 / Day 1 1.5h SER-1
Nicotine	11	Fail	AA97220-01 05104620000765 10 N/A 13 / Day 1 1.5h SER-1
Nicotine	11	Fail	AA97220-01 05104620000766 10 N/A 14 / Day 1 2h SER-1
Nicotine	11	Fail	AA97220-01 05104620000782 10 N/A 14 / Day 1 2h SER-1
Nicotine	11	Fail	AA97220-01 05104620000798 10 N/A 14 / Day 1 2h SER-1
Nicotine	11	Fail	AA97220-01 05104620000783 10 N/A 15 / Day 1 2.5h SER-1
Nicotine	11	Fail	AA97220-01 05104620000799 10 N/A 15 / Day 1 2.5h SER-1
Nicotine	11	Fail	AA97220-01 05104620000767 10 N/A 15 / Day 1 2.5h SER-1
Nicotine	11	Fail	AA97220-01 05104620000800 10 N/A 16 / Day 1 3h SER-1
Nicotine	11	Fail	AA97220-01 05104620000784 10 N/A 16 / Day 1 3h SER-1
Nicotine	11	Fail	AA97220-01 05104620000768 10 N/A 16 / Day 1 3h SER-1
Nicotine	15	Fail	AA97220-01 05104620000993 13 N/A 1 / Day 1 -0.0333h SER-1
Nicotine	15	Fail	AA97220-01 05104620001025 13 N/A 1 / Day 1 -0.0333h SER-1
Nicotine	15	Fail	AA97220-01 05104620001009 13 N/A 1 / Day 1 -0.0333h SER-1
Nicotine	15	Fail	AA97220-01 05104620000977 13 N/A 1 / Day 1 -0.0333h SER-1
Nicotine	15	Fail	AA97220-01 05104620001010 13 N/A 2 / Day 1 0h SER-1
Nicotine	15	Fail	AA97220-01 05104620000994 13 N/A 2 / Day 1 0h SER-1
Nicotine	15	Fail	AA97220-01 05104620000978 13 N/A 2 / Day 1 0h SER-1
Nicotine	15	Fail	AA97220-01 05104620001026 13 N/A 2 / Day 1 0h SER-1
Nicotine	15	Fail	AA97220-01 05104620001027 13 N/A 3 / Day 1 0.05h SER-1
Nicotine	15	Fail	AA97220-01 05104620000979 13 N/A 3 / Day 1 0.05h SER-1
Nicotine	15	Fail	AA97220-01 05104620001011 13 N/A 3 / Day 1 0.05h SER-1
Nicotine	15	Fail	AA97220-01 05104620000995 13 N/A 3 / Day 1 0.05h SER-1
Nicotine	15	Fail	AA97220-01 05104620000980 13 N/A 4 / Day 1 0.0833h SER-1
Nicotine	15	Fail	AA97220-01 05104620001028 13 N/A 4 / Day 1 0.0833h SER-1
Nicotine	15	Fail	AA97220-01 05104620000996 13 N/A 4 / Day 1 0.0833h SER-1

Analyte	Batch Number	Reason	Sample Name
Nicotine	15	Fail	AA97220-01 05104620001012 13 N/A 4 / Day 1 0.0833h SER-1
Nicotine	15	Fail	AA97220-01 05104620001013 13 N/A 5 / Day 1 0.125h SER-1
Nicotine	15	Fail	AA97220-01 05104620000981 13 N/A 5 / Day 1 0.125h SER-1
Nicotine	15	Fail	AA97220-01 05104620000997 13 N/A 5 / Day 1 0.125h SER-1
Nicotine	15	Fail	AA97220-01 05104620001029 13 N/A 5 / Day 1 0.125h SER-1
Nicotine	15	Fail	AA97220-01 05104620000982 13 N/A 6 / Day 1 0.1667h SER-1
Nicotine	15	ISA/Fail	AA97220-01 05104620001030 13 N/A 6 / Day 1 0.1667h SER-1
Nicotine	15	Fail	AA97220-01 05104620000998 13 N/A 6 / Day 1 0.1667h SER-1
Nicotine	15	Fail	AA97220-01 05104620001014 13 N/A 6 / Day 1 0.1667h SER-1
Nicotine	15	Fail	AA97220-01 05104620001031 13 N/A 7 / Day 1 0.25h SER-1
Nicotine	15	Fail	AA97220-01 05104620001015 13 N/A 7 / Day 1 0.25h SER-1
Nicotine	15	Fail	AA97220-01 05104620000983 13 N/A 7 / Day 1 0.25h SER-1
Nicotine	15	Fail	AA97220-01 05104620000999 13 N/A 7 / Day 1 0.25h SER-1
Nicotine	15	Fail	AA97220-01 05104620001032 13 N/A 8 / Day 1 0.333h SER-1
Nicotine	15	Fail	AA97220-01 05104620001000 13 N/A 8 / Day 1 0.333h SER-1
Nicotine	15	Fail	AA97220-01 05104620000984 13 N/A 8 / Day 1 0.333h SER-1
Nicotine	15	Fail	AA97220-01 05104620001016 13 N/A 8 / Day 1 0.333h SER-1
Nicotine	15	Fail	AA97220-01 05104620001033 13 N/A 9 / Day 1 0.5h SER-1
Nicotine	15	Fail	AA97220-01 05104620001017 13 N/A 9 / Day 1 0.5h SER-1
Nicotine	15	Fail	AA97220-01 05104620000985 13 N/A 9 / Day 1 0.5h SER-1
Nicotine	15	Fail	AA97220-01 05104620001001 13 N/A 9 / Day 1 0.5h SER-1
Nicotine	15	Fail	AA97220-01 05104620000986 13 N/A 10 / Day 1 0.75h SER-1
Nicotine	15	Fail	AA97220-01 05104620001034 13 N/A 10 / Day 1 0.75h SER-1
Nicotine	15	Fail	AA97220-01 05104620001018 13 N/A 10 / Day 1 0.75h SER-1
Nicotine	15	Fail	AA97220-01 05104620001002 13 N/A 10 / Day 1 0.75h SER-1
Nicotine	15	Fail	AA97220-01 05104620001035 13 N/A 11 / Day 1 1h SER-1
Nicotine	15	Fail	AA97220-01 05104620001003 13 N/A 11 / Day 1 1h SER-1
Nicotine	15	Fail	AA97220-01 05104620001019 13 N/A 11 / Day 1 1h SER-1
Nicotine	15	Fail	AA97220-01 05104620000987 13 N/A 11 / Day 1 1h SER-1
Nicotine	15	Fail	AA97220-01 05104620001036 13 N/A 12 / Day 1 1.25h SER-1
Nicotine	15	Fail	AA97220-01 05104620000988 13 N/A 12 / Day 1 1.25h SER-1
Nicotine	15	Fail	AA97220-01 05104620001020 13 N/A 12 / Day 1 1.25h SER-1
Nicotine	15	Fail	AA97220-01 05104620001004 13 N/A 12 / Day 1 1.25h SER-1
Nicotine	15	Fail	AA97220-01 05104620001021 13 N/A 13 / Day 1 1.5h SER-1
Nicotine	15	Fail	AA97220-01 05104620000989 13 N/A 13 / Day 1 1.5h SER-1
Nicotine	15	Fail	AA97220-01 05104620001037 13 N/A 13 / Day 1 1.5h SER-1
Nicotine	15	Fail	AA97220-01 05104620001005 13 N/A 13 / Day 1 1.5h SER-1
Nicotine	15	Fail	AA97220-01 05104620001022 13 N/A 14 / Day 1 2h SER-1
Nicotine	15	Fail	AA97220-01 05104620000990 13 N/A 14 / Day 1 2h SER-1
Nicotine	15	Fail	AA97220-01 05104620001006 13 N/A 14 / Day 1 2h SER-1
Nicotine	15	Fail	AA97220-01 05104620001038 13 N/A 14 / Day 1 2h SER-1
Nicotine	15	Fail	AA97220-01 05104620001023 13 N/A 15 / Day 1 2.5h SER-1
Nicotine	15	Fail	AA97220-01 05104620001007 13 N/A 15 / Day 1 2.5h SER-1

Analyte	Batch Number	Reason	Sample Name
Nicotine	15	Fail	AA97220-01 05104620000991 13 N/A 15 / Day 1 2.5h SER-1
Nicotine	15	Fail	AA97220-01 05104620001039 13 N/A 15 / Day 1 2.5h SER-1
Nicotine	15	Fail	AA97220-01 05104620001008 13 N/A 16 / Day 1 3h SER-1
Nicotine	15	Fail	AA97220-01 05104620000992 13 N/A 16 / Day 1 3h SER-1
Nicotine	15	Fail	AA97220-01 05104620001024 13 N/A 16 / Day 1 3h SER-1
Nicotine	15	Fail	AA97220-01 05104620001040 13 N/A 16 / Day 1 3h SER-1
Nicotine	16	UISR	AA97220-01 05104620000971 13 N/A 11 / Day 1 1h SER-1
Nicotine	16	UISR	AA97220-01 05104620001088 14 N/A 16 / Day 1 3h SER-1
Nicotine	18	UISR	AA97220-01 05104620001266 16 N/A 2 / Day 1 0h SER-1
Nicotine	18	UISR	AA97220-01 05104620001267 16 N/A 3 / Day 1 0.05h SER-1
Nicotine	33	DCU	AA97220-01 05104620001088 14 N/A 16 / Day 1 3h SER-1
Nicotine	38	DCU	AA97220-01 05104620000848 11 N/A 16 / Day 1 3h SER-1
Cotinine	1	UISR	AA97220-01 05104620000047 01 N/A 15 / Day 1 2.5h SER-1
Cotinine	3	AAR	AA97220-01 05104620000209 03 N/A 1 / Day 1 -0.0333h SER-1
Cotinine	3	AAR	AA97220-01 05104620000225 03 N/A 1 / Day 1 -0.0333h SER-1
Cotinine	3	AAR	AA97220-01 05104620000210 03 N/A 2 / Day 1 0h SER-1
Cotinine	3	AAR	AA97220-01 05104620000226 03 N/A 2 / Day 1 0h SER-1
Cotinine	3	AAR	AA97220-01 05104620000227 03 N/A 3 / Day 1 0.05h SER-1
Cotinine	3	AAR	AA97220-01 05104620000211 03 N/A 3 / Day 1 0.05h SER-1
Cotinine	3	AAR	AA97220-01 05104620000228 03 N/A 4 / Day 1 0.0833h SER-1
Cotinine	3	AAR	AA97220-01 05104620000212 03 N/A 4 / Day 1 0.0833h SER-1
Cotinine	3	AAR	AA97220-01 05104620000213 03 N/A 5 / Day 1 0.125h SER-1
Cotinine	3	AAR	AA97220-01 05104620000214 03 N/A 6 / Day 1 0.1667h SER-1
Cotinine	3	AAR	AA97220-01 05104620000215 03 N/A 7 / Day 1 0.25h SER-1
Cotinine	3	AAR	AA97220-01 05104620000231 03 N/A 7 / Day 1 0.25h SER-1
Cotinine	3	AAR	AA97220-01 05104620000232 03 N/A 8 / Day 1 0.333h SER-1
Cotinine	3	AAR	AA97220-01 05104620000216 03 N/A 8 / Day 1 0.333h SER-1
Cotinine	3	AAR	AA97220-01 05104620000233 03 N/A 9 / Day 1 0.5h SER-1
Cotinine	3	AAR	AA97220-01 05104620000217 03 N/A 9 / Day 1 0.5h SER-1
Cotinine	3	AAR	AA97220-01 05104620000234 03 N/A 10 / Day 1 0.75h SER-1
Cotinine	3	AAR	AA97220-01 05104620000218 03 N/A 10 / Day 1 0.75h SER-1
Cotinine	3	AAR	AA97220-01 05104620000235 03 N/A 11 / Day 1 1h SER-1
Cotinine	3	AAR	AA97220-01 05104620000219 03 N/A 11 / Day 1 1h SER-1
Cotinine	3	AAR	AA97220-01 05104620000220 03 N/A 12 / Day 1 1.25h SER-1
Cotinine	3	AAR	AA97220-01 05104620000236 03 N/A 12 / Day 1 1.25h SER-1
Cotinine	3	AAR	AA97220-01 05104620000237 03 N/A 13 / Day 1 1.5h SER-1
Cotinine	3	AAR	AA97220-01 05104620000221 03 N/A 13 / Day 1 1.5h SER-1
Cotinine	3	AAR	AA97220-01 05104620000238 03 N/A 14 / Day 1 2h SER-1
Cotinine	3	AAR	AA97220-01 05104620000222 03 N/A 14 / Day 1 2h SER-1
Cotinine	3	AAR	AA97220-01 05104620000239 03 N/A 15 / Day 1 2.5h SER-1
Cotinine	3	AAR	AA97220-01 05104620000223 03 N/A 15 / Day 1 2.5h SER-1
Cotinine	3	AAR	AA97220-01 05104620000240 03 N/A 16 / Day 1 3h SER-1
Cotinine	3	AAR	AA97220-01 05104620000224 03 N/A 16 / Day 1 3h SER-1

Analyte	Batch Number	Reason	Sample Name
Cotinine	4	AAR	AA97220-01 05104620000161 03 N/A 1 / Day 1 -0.0333h SER-1
Cotinine	4	AAR	AA97220-01 05104620000177 03 N/A 1 / Day 1 -0.0333h SER-1
Cotinine	4	AAR	AA97220-01 05104620000193 03 N/A 1 / Day 1 -0.0333h SER-1
Cotinine	4	AAR	AA97220-01 05104620000162 03 N/A 2 / Day 1 0h SER-1
Cotinine	4	AAR	AA97220-01 05104620000178 03 N/A 2 / Day 1 0h SER-1
Cotinine	4	AAR	AA97220-01 05104620000194 03 N/A 2 / Day 1 0h SER-1
Cotinine	4	AAR	AA97220-01 05104620000163 03 N/A 3 / Day 1 0.05h SER-1
Cotinine	4	AAR	AA97220-01 05104620000195 03 N/A 3 / Day 1 0.05h SER-1
Cotinine	4	AAR	AA97220-01 05104620000179 03 N/A 3 / Day 1 0.05h SER-1
Cotinine	4	AAR	AA97220-01 05104620000196 03 N/A 4 / Day 1 0.0833h SER-1
Cotinine	4	AAR	AA97220-01 05104620000180 03 N/A 4 / Day 1 0.0833h SER-1
Cotinine	4	AAR	AA97220-01 05104620000164 03 N/A 4 / Day 1 0.0833h SER-1
Cotinine	4	AAR	AA97220-01 05104620000197 03 N/A 5 / Day 1 0.125h SER-1
Cotinine	4	AAR	AA97220-01 05104620000181 03 N/A 5 / Day 1 0.125h SER-1
Cotinine	4	AAR	AA97220-01 05104620000165 03 N/A 5 / Day 1 0.125h SER-1
Cotinine	4	AAR	AA97220-01 05104620000166 03 N/A 6 / Day 1 0.1667h SER-1
Cotinine	4	AAR	AA97220-01 05104620000198 03 N/A 6 / Day 1 0.1667h SER-1
Cotinine	4	AAR	AA97220-01 05104620000182 03 N/A 6 / Day 1 0.1667h SER-1
Cotinine	4	AAR	AA97220-01 05104620000167 03 N/A 7 / Day 1 0.25h SER-1
Cotinine	4	AAR	AA97220-01 05104620000183 03 N/A 7 / Day 1 0.25h SER-1
Cotinine	4	AAR	AA97220-01 05104620000199 03 N/A 7 / Day 1 0.25h SER-1
Cotinine	4	AAR	AA97220-01 05104620000184 03 N/A 8 / Day 1 0.333h SER-1
Cotinine	4	AAR	AA97220-01 05104620000168 03 N/A 8 / Day 1 0.333h SER-1
Cotinine	4	AAR	AA97220-01 05104620000200 03 N/A 8 / Day 1 0.333h SER-1
Cotinine	4	AAR	AA97220-01 05104620000201 03 N/A 9 / Day 1 0.5h SER-1
Cotinine	4	AAR	AA97220-01 05104620000185 03 N/A 9 / Day 1 0.5h SER-1
Cotinine	4	AAR	AA97220-01 05104620000169 03 N/A 9 / Day 1 0.5h SER-1
Cotinine	4	AAR	AA97220-01 05104620000202 03 N/A 10 / Day 1 0.75h SER-1
Cotinine	4	AAR	AA97220-01 05104620000170 03 N/A 10 / Day 1 0.75h SER-1
Cotinine	4	AAR	AA97220-01 05104620000186 03 N/A 10 / Day 1 0.75h SER-1
Cotinine	4	AAR	AA97220-01 05104620000203 03 N/A 11 / Day 1 1h SER-1
Cotinine	4	AAR	AA97220-01 05104620000171 03 N/A 11 / Day 1 1h SER-1
Cotinine	4	AAR	AA97220-01 05104620000187 03 N/A 11 / Day 1 1h SER-1
Cotinine	4	AAR	AA97220-01 05104620000204 03 N/A 12 / Day 1 1.25h SER-1
Cotinine	4	AAR	AA97220-01 05104620000172 03 N/A 12 / Day 1 1.25h SER-1
Cotinine	4	AAR	AA97220-01 05104620000188 03 N/A 12 / Day 1 1.25h SER-1
Cotinine	4	AAR	AA97220-01 05104620000189 03 N/A 13 / Day 1 1.5h SER-1
Cotinine	4	AAR	AA97220-01 05104620000205 03 N/A 13 / Day 1 1.5h SER-1
Cotinine	4	AAR	AA97220-01 05104620000173 03 N/A 13 / Day 1 1.5h SER-1
Cotinine	4	AAR	AA97220-01 05104620000174 03 N/A 14 / Day 1 2h SER-1
Cotinine	4	AAR	AA97220-01 05104620000206 03 N/A 14 / Day 1 2h SER-1
Cotinine	4	AAR	AA97220-01 05104620000190 03 N/A 14 / Day 1 2h SER-1
Cotinine	4	AAR	AA97220-01 05104620000175 03 N/A 15 / Day 1 2.5h SER-1

Analyte	Batch Number	Reason	Sample Name
Cotinine	4	AAR	AA97220-01 05104620000191 03 N/A 15 / Day 1 2.5h SER-1
Cotinine	4	AAR	AA97220-01 05104620000207 03 N/A 15 / Day 1 2.5h SER-1
Cotinine	4	AAR	AA97220-01 05104620000176 03 N/A 16 / Day 1 3h SER-1
Cotinine	4	AAR	AA97220-01 05104620000208 03 N/A 16 / Day 1 3h SER-1
Cotinine	4	AAR	AA97220-01 05104620000192 03 N/A 16 / Day 1 3h SER-1
Cotinine	4	UISR	AA97220-01 05104620000314 04 N/A 10 / Day 1 0.75h SER-1
Cotinine	6	AAR	AA97220-01 05104620000369 05 N/A 1 / Day 1 -0.0333h SER-1
Cotinine	6	AAR	AA97220-01 05104620000370 05 N/A 2 / Day 1 0h SER-1
Cotinine	6	AAR	AA97220-01 05104620000371 05 N/A 3 / Day 1 0.05h SER-1
Cotinine	6	AAR	AA97220-01 05104620000372 05 N/A 4 / Day 1 0.0833h SER-1
Cotinine	6	AAR	AA97220-01 05104620000373 05 N/A 5 / Day 1 0.125h SER-1
Cotinine	6	AAR	AA97220-01 05104620000374 05 N/A 6 / Day 1 0.1667h SER-1
Cotinine	6	AAR	AA97220-01 05104620000375 05 N/A 7 / Day 1 0.25h SER-1
Cotinine	6	AAR	AA97220-01 05104620000376 05 N/A 8 / Day 1 0.333h SER-1
Cotinine	6	AAR	AA97220-01 05104620000377 05 N/A 9 / Day 1 0.5h SER-1
Cotinine	6	AAR	AA97220-01 05104620000378 05 N/A 10 / Day 1 0.75h SER-1
Cotinine	6	AAR	AA97220-01 05104620000379 05 N/A 11 / Day 1 1h SER-1
Cotinine	6	AAR	AA97220-01 05104620000380 05 N/A 12 / Day 1 1.25h SER-1
Cotinine	10	Fail	AA97220-01 05104620000705 09 N/A 1 / Day 1 -0.0333h SER-1
Cotinine	10	AAR/Fail	AA97220-01 05104620000657 09 N/A 1 / Day 1 -0.0333h SER-1
Cotinine	10	AAR/Fail	AA97220-01 05104620000673 09 N/A 1 / Day 1 -0.0333h SER-1
Cotinine	10	AAR/Fail	AA97220-01 05104620000689 09 N/A 1 / Day 1 -0.0333h SER-1
Cotinine	10	AAR/Fail	AA97220-01 05104620000706 09 N/A 2 / Day 1 0h SER-1
Cotinine	10	AAR/Fail	AA97220-01 05104620000690 09 N/A 2 / Day 1 0h SER-1
Cotinine	10	AAR/Fail	AA97220-01 05104620000674 09 N/A 2 / Day 1 0h SER-1
Cotinine	10	AAR/Fail	AA97220-01 05104620000658 09 N/A 2 / Day 1 0h SER-1
Cotinine	10	Fail	AA97220-01 05104620000659 09 N/A 3 / Day 1 0.05h SER-1
Cotinine	10	AAR/Fail	AA97220-01 05104620000675 09 N/A 3 / Day 1 0.05h SER-1
Cotinine	10	AAR/Fail	AA97220-01 05104620000691 09 N/A 3 / Day 1 0.05h SER-1
Cotinine	10	AAR/Fail	AA97220-01 05104620000707 09 N/A 3 / Day 1 0.05h SER-1
Cotinine	10	AAR/Fail	AA97220-01 05104620000676 09 N/A 4 / Day 1 0.0833h SER-1
Cotinine	10	AAR/Fail	AA97220-01 05104620000708 09 N/A 4 / Day 1 0.0833h SER-1
Cotinine	10	AAR/Fail	AA97220-01 05104620000660 09 N/A 4 / Day 1 0.0833h SER-1
Cotinine	10	AAR/Fail	AA97220-01 05104620000692 09 N/A 4 / Day 1 0.0833h SER-1
Cotinine	10	AAR/Fail	AA97220-01 05104620000693 09 N/A 5 / Day 1 0.125h SER-1
Cotinine	10	AAR/Fail	AA97220-01 05104620000709 09 N/A 5 / Day 1 0.125h SER-1
Cotinine	10	AAR/Fail	AA97220-01 05104620000661 09 N/A 5 / Day 1 0.125h SER-1
Cotinine	10	AAR/Fail	AA97220-01 05104620000677 09 N/A 5 / Day 1 0.125h SER-1
Cotinine	10	AAR/Fail	AA97220-01 05104620000710 09 N/A 6 / Day 1 0.1667h SER-1
Cotinine	10	AAR/Fail	AA97220-01 05104620000694 09 N/A 6 / Day 1 0.1667h SER-1
Cotinine	10	AAR/Fail	AA97220-01 05104620000662 09 N/A 6 / Day 1 0.1667h SER-1
Cotinine	10	AAR/Fail	AA97220-01 05104620000678 09 N/A 6 / Day 1 0.1667h SER-1
Cotinine	10	AAR/Fail	AA97220-01 05104620000695 09 N/A 7 / Day 1 0.25h SER-1

Analyte	Batch Number	Reason	Sample Name
Cotinine	10	AAR/Fail	AA97220-01 05104620000679 09 N/A 7 / Day 1 0.25h SER-1
Cotinine	10	AAR/Fail	AA97220-01 05104620000663 09 N/A 7 / Day 1 0.25h SER-1
Cotinine	10	AAR/Fail	AA97220-01 05104620000711 09 N/A 7 / Day 1 0.25h SER-1
Cotinine	10	AAR/Fail	AA97220-01 05104620000680 09 N/A 8 / Day 1 0.333h SER-1
Cotinine	10	AAR/Fail	AA97220-01 05104620000696 09 N/A 8 / Day 1 0.333h SER-1
Cotinine	10	AAR/Fail	AA97220-01 05104620000712 09 N/A 8 / Day 1 0.333h SER-1
Cotinine	10	Fail	AA97220-01 05104620000664 09 N/A 8 / Day 1 0.333h SER-1
Cotinine	10	AAR/Fail	AA97220-01 05104620000681 09 N/A 9 / Day 1 0.5h SER-1
Cotinine	10	AAR/Fail	AA97220-01 05104620000665 09 N/A 9 / Day 1 0.5h SER-1
Cotinine	10	AAR/Fail	AA97220-01 05104620000697 09 N/A 9 / Day 1 0.5h SER-1
Cotinine	10	AAR/Fail	AA97220-01 05104620000713 09 N/A 9 / Day 1 0.5h SER-1
Cotinine	10	AAR/Fail	AA97220-01 05104620000666 09 N/A 10 / Day 1 0.75h SER-1
Cotinine	10	AAR/Fail	AA97220-01 05104620000682 09 N/A 10 / Day 1 0.75h SER-1
Cotinine	10	AAR/Fail	AA97220-01 05104620000698 09 N/A 10 / Day 1 0.75h SER-1
Cotinine	10	AAR/Fail	AA97220-01 05104620000714 09 N/A 10 / Day 1 0.75h SER-1
Cotinine	10	AAR/Fail	AA97220-01 05104620000683 09 N/A 11 / Day 1 1h SER-1
Cotinine	10	Fail	AA97220-01 05104620000715 09 N/A 11 / Day 1 1h SER-1
Cotinine	10	AAR/Fail	AA97220-01 05104620000699 09 N/A 11 / Day 1 1h SER-1
Cotinine	10	AAR/Fail	AA97220-01 05104620000667 09 N/A 11 / Day 1 1h SER-1
Cotinine	10	AAR/Fail	AA97220-01 05104620000700 09 N/A 12 / Day 1 1.25h SER-1
Cotinine	10	Fail	AA97220-01 05104620000684 09 N/A 12 / Day 1 1.25h SER-1
Cotinine	10	AAR/Fail	AA97220-01 05104620000716 09 N/A 12 / Day 1 1.25h SER-1
Cotinine	10	Fail	AA97220-01 05104620000668 09 N/A 12 / Day 1 1.25h SER-1
Cotinine	10	AAR/Fail	AA97220-01 05104620000717 09 N/A 13 / Day 1 1.5h SER-1
Cotinine	10	Fail	AA97220-01 05104620000669 09 N/A 13 / Day 1 1.5h SER-1
Cotinine	10	Fail	AA97220-01 05104620000685 09 N/A 13 / Day 1 1.5h SER-1
Cotinine	10	AAR/Fail	AA97220-01 05104620000701 09 N/A 13 / Day 1 1.5h SER-1
Cotinine	10	AAR/Fail	AA97220-01 05104620000702 09 N/A 14 / Day 1 2h SER-1
Cotinine	10	Fail	AA97220-01 05104620000718 09 N/A 14 / Day 1 2h SER-1
Cotinine	10	Fail	AA97220-01 05104620000670 09 N/A 14 / Day 1 2h SER-1
Cotinine	10	Fail	AA97220-01 05104620000686 09 N/A 14 / Day 1 2h SER-1
Cotinine	10	Fail	AA97220-01 05104620000687 09 N/A 15 / Day 1 2.5h SER-1
Cotinine	10	AAR/Fail	AA97220-01 05104620000719 09 N/A 15 / Day 1 2.5h SER-1
Cotinine	10	AAR/Fail	AA97220-01 05104620000703 09 N/A 15 / Day 1 2.5h SER-1
Cotinine	10	Fail	AA97220-01 05104620000671 09 N/A 15 / Day 1 2.5h SER-1
Cotinine	10	AAR/Fail	AA97220-01 05104620000704 09 N/A 16 / Day 1 3h SER-1
Cotinine	10	Fail	AA97220-01 05104620000720 09 N/A 16 / Day 1 3h SER-1
Cotinine	10	Fail	AA97220-01 05104620000672 09 N/A 16 / Day 1 3h SER-1
Cotinine	10	Fail	AA97220-01 05104620000688 09 N/A 16 / Day 1 3h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000641 09 N/A 1 / Day 1 -0.0333h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000642 09 N/A 2 / Day 1 0h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000643 09 N/A 3 / Day 1 0.05h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000644 09 N/A 4 / Day 1 0.0833h SER-1

Analyte	Batch Number	Reason	Sample Name
Cotinine	11	AAR/Fail	AA97220-01 05104620000645 09 N/A 5 / Day 1 0.125h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000646 09 N/A 6 / Day 1 0.1667h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000647 09 N/A 7 / Day 1 0.25h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000648 09 N/A 8 / Day 1 0.333h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000649 09 N/A 9 / Day 1 0.5h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000650 09 N/A 10 / Day 1 0.75h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000651 09 N/A 11 / Day 1 1h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000652 09 N/A 12 / Day 1 1.25h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000653 09 N/A 13 / Day 1 1.5h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000654 09 N/A 14 / Day 1 2h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000655 09 N/A 15 / Day 1 2.5h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000656 09 N/A 16 / Day 1 3h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000785 10 N/A 1 / Day 1 -0.0333h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000753 10 N/A 1 / Day 1 -0.0333h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000769 10 N/A 1 / Day 1 -0.0333h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000770 10 N/A 2 / Day 1 0h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000754 10 N/A 2 / Day 1 0h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000786 10 N/A 2 / Day 1 0h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000755 10 N/A 3 / Day 1 0.05h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000771 10 N/A 3 / Day 1 0.05h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000787 10 N/A 3 / Day 1 0.05h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000772 10 N/A 4 / Day 1 0.0833h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000756 10 N/A 4 / Day 1 0.0833h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000788 10 N/A 4 / Day 1 0.0833h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000773 10 N/A 5 / Day 1 0.125h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000789 10 N/A 5 / Day 1 0.125h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000757 10 N/A 5 / Day 1 0.125h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000790 10 N/A 6 / Day 1 0.1667h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000758 10 N/A 6 / Day 1 0.1667h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000774 10 N/A 6 / Day 1 0.1667h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000759 10 N/A 7 / Day 1 0.25h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000775 10 N/A 7 / Day 1 0.25h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000791 10 N/A 7 / Day 1 0.25h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000760 10 N/A 8 / Day 1 0.333h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000776 10 N/A 8 / Day 1 0.333h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000792 10 N/A 8 / Day 1 0.333h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000793 10 N/A 9 / Day 1 0.5h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000761 10 N/A 9 / Day 1 0.5h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000777 10 N/A 9 / Day 1 0.5h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000762 10 N/A 10 / Day 1 0.75h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000794 10 N/A 10 / Day 1 0.75h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000778 10 N/A 10 / Day 1 0.75h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000795 10 N/A 11 / Day 1 1h SER-1

Analyte	Batch Number	Reason	Sample Name
Cotinine	11	AAR/Fail	AA97220-01 05104620000763 10 N/A 11 / Day 1 1h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000779 10 N/A 11 / Day 1 1h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000780 10 N/A 12 / Day 1 1.25h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000796 10 N/A 12 / Day 1 1.25h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000764 10 N/A 12 / Day 1 1.25h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000781 10 N/A 13 / Day 1 1.5h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000797 10 N/A 13 / Day 1 1.5h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000765 10 N/A 13 / Day 1 1.5h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000766 10 N/A 14 / Day 1 2h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000782 10 N/A 14 / Day 1 2h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000798 10 N/A 14 / Day 1 2h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000783 10 N/A 15 / Day 1 2.5h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000799 10 N/A 15 / Day 1 2.5h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000767 10 N/A 15 / Day 1 2.5h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000800 10 N/A 16 / Day 1 3h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000784 10 N/A 16 / Day 1 3h SER-1
Cotinine	11	AAR/Fail	AA97220-01 05104620000768 10 N/A 16 / Day 1 3h SER-1
Cotinine	12	AAR	AA97220-01 05104620000721 10 N/A 1 / Day 1 -0.0333h SER-1
Cotinine	12	AAR	AA97220-01 05104620000737 10 N/A 1 / Day 1 -0.0333h SER-1
Cotinine	12	AAR	AA97220-01 05104620000722 10 N/A 2 / Day 1 0h SER-1
Cotinine	12	AAR	AA97220-01 05104620000738 10 N/A 2 / Day 1 0h SER-1
Cotinine	12	AAR	AA97220-01 05104620000739 10 N/A 3 / Day 1 0.05h SER-1
Cotinine	12	AAR	AA97220-01 05104620000723 10 N/A 3 / Day 1 0.05h SER-1
Cotinine	12	AAR	AA97220-01 05104620000740 10 N/A 4 / Day 1 0.0833h SER-1
Cotinine	12	AAR	AA97220-01 05104620000724 10 N/A 4 / Day 1 0.0833h SER-1
Cotinine	12	AAR	AA97220-01 05104620000725 10 N/A 5 / Day 1 0.125h SER-1
Cotinine	12	AAR	AA97220-01 05104620000741 10 N/A 5 / Day 1 0.125h SER-1
Cotinine	12	AAR	AA97220-01 05104620000742 10 N/A 6 / Day 1 0.1667h SER-1
Cotinine	12	AAR	AA97220-01 05104620000726 10 N/A 6 / Day 1 0.1667h SER-1
Cotinine	12	AAR	AA97220-01 05104620000727 10 N/A 7 / Day 1 0.25h SER-1
Cotinine	12	AAR	AA97220-01 05104620000743 10 N/A 7 / Day 1 0.25h SER-1
Cotinine	12	AAR	AA97220-01 05104620000728 10 N/A 8 / Day 1 0.333h SER-1
Cotinine	12	AAR	AA97220-01 05104620000744 10 N/A 8 / Day 1 0.333h SER-1
Cotinine	12	AAR	AA97220-01 05104620000745 10 N/A 9 / Day 1 0.5h SER-1
Cotinine	12	AAR	AA97220-01 05104620000729 10 N/A 9 / Day 1 0.5h SER-1
Cotinine	12	AAR	AA97220-01 05104620000746 10 N/A 10 / Day 1 0.75h SER-1
Cotinine	12	AAR	AA97220-01 05104620000730 10 N/A 10 / Day 1 0.75h SER-1
Cotinine	12	AAR	AA97220-01 05104620000731 10 N/A 11 / Day 1 1h SER-1
Cotinine	12	AAR	AA97220-01 05104620000747 10 N/A 11 / Day 1 1h SER-1
Cotinine	12	AAR	AA97220-01 05104620000732 10 N/A 12 / Day 1 1.25h SER-1
Cotinine	12	AAR	AA97220-01 05104620000748 10 N/A 12 / Day 1 1.25h SER-1
Cotinine	12	AAR	AA97220-01 05104620000749 10 N/A 13 / Day 1 1.5h SER-1
Cotinine	12	AAR	AA97220-01 05104620000733 10 N/A 13 / Day 1 1.5h SER-1

Analyte	Batch Number	Reason	Sample Name
Cotinine	12	AAR	AA97220-01 05104620000750 10 N/A 14 / Day 1 2h SER-1
Cotinine	12	AAR	AA97220-01 05104620000734 10 N/A 14 / Day 1 2h SER-1
Cotinine	12	AAR	AA97220-01 05104620000751 10 N/A 15 / Day 1 2.5h SER-1
Cotinine	12	AAR	AA97220-01 05104620000735 10 N/A 15 / Day 1 2.5h SER-1
Cotinine	12	AAR	AA97220-01 05104620000736 10 N/A 16 / Day 1 3h SER-1
Cotinine	12	AAR	AA97220-01 05104620000752 10 N/A 16 / Day 1 3h SER-1
Cotinine	12	AAR	AA97220-01 05104620000865 11 N/A 1 / Day 1 -0.0333h SER-1
Cotinine	12	AAR	AA97220-01 05104620000866 11 N/A 2 / Day 1 0h SER-1
Cotinine	12	AAR	AA97220-01 05104620000867 11 N/A 3 / Day 1 0.05h SER-1
Cotinine	12	AAR	AA97220-01 05104620000868 11 N/A 4 / Day 1 0.0833h SER-1
Cotinine	12	AAR	AA97220-01 05104620000869 11 N/A 5 / Day 1 0.125h SER-1
Cotinine	12	AAR	AA97220-01 05104620000870 11 N/A 6 / Day 1 0.1667h SER-1
Cotinine	12	AAR	AA97220-01 05104620000871 11 N/A 7 / Day 1 0.25h SER-1
Cotinine	12	AAR	AA97220-01 05104620000872 11 N/A 8 / Day 1 0.333h SER-1
Cotinine	12	AAR	AA97220-01 05104620000873 11 N/A 9 / Day 1 0.5h SER-1
Cotinine	12	AAR	AA97220-01 05104620000874 11 N/A 10 / Day 1 0.75h SER-1
Cotinine	12	AAR	AA97220-01 05104620000875 11 N/A 11 / Day 1 1h SER-1
Cotinine	12	AAR	AA97220-01 05104620000876 11 N/A 12 / Day 1 1.25h SER-1
Cotinine	12	AAR	AA97220-01 05104620000877 11 N/A 13 / Day 1 1.5h SER-1
Cotinine	12	AAR	AA97220-01 05104620000878 11 N/A 14 / Day 1 2h SER-1
Cotinine	12	AAR	AA97220-01 05104620000879 11 N/A 15 / Day 1 2.5h SER-1
Cotinine	12	AAR	AA97220-01 05104620000880 11 N/A 16 / Day 1 3h SER-1
Cotinine	13	AAR	AA97220-01 05104620000817 11 N/A 1 / Day 1 -0.0333h SER-1
Cotinine	13	AAR	AA97220-01 05104620000818 11 N/A 2 / Day 1 0h SER-1
Cotinine	13	AAR	AA97220-01 05104620000819 11 N/A 3 / Day 1 0.05h SER-1
Cotinine	13	AAR	AA97220-01 05104620000820 11 N/A 4 / Day 1 0.0833h SER-1
Cotinine	13	AAR	AA97220-01 05104620000821 11 N/A 5 / Day 1 0.125h SER-1
Cotinine	13	AAR	AA97220-01 05104620000822 11 N/A 6 / Day 1 0.1667h SER-1
Cotinine	13	AAR	AA97220-01 05104620000823 11 N/A 7 / Day 1 0.25h SER-1
Cotinine	13	AAR	AA97220-01 05104620000824 11 N/A 8 / Day 1 0.333h SER-1
Cotinine	13	AAR	AA97220-01 05104620000825 11 N/A 9 / Day 1 0.5h SER-1
Cotinine	13	AAR	AA97220-01 05104620000826 11 N/A 10 / Day 1 0.75h SER-1
Cotinine	13	AAR	AA97220-01 05104620000827 11 N/A 11 / Day 1 1h SER-1
Cotinine	13	AAR	AA97220-01 05104620000828 11 N/A 12 / Day 1 1.25h SER-1
Cotinine	13	AAR	AA97220-01 05104620000829 11 N/A 13 / Day 1 1.5h SER-1
Cotinine	13	AAR	AA97220-01 05104620000830 11 N/A 14 / Day 1 2h SER-1
Cotinine	13	AAR	AA97220-01 05104620000831 11 N/A 15 / Day 1 2.5h SER-1
Cotinine	13	AAR	AA97220-01 05104620000832 11 N/A 16 / Day 1 3h SER-1
Cotinine	13	AAR	AA97220-01 05104620000945 12 N/A 1 / Day 1 -0.0333h SER-1
Cotinine	13	AAR	AA97220-01 05104620000946 12 N/A 2 / Day 1 0h SER-1
Cotinine	13	AAR	AA97220-01 05104620000947 12 N/A 3 / Day 1 0.05h SER-1
Cotinine	13	AAR	AA97220-01 05104620000948 12 N/A 4 / Day 1 0.0833h SER-1
Cotinine	13	AAR	AA97220-01 05104620000949 12 N/A 5 / Day 1 0.125h SER-1

Analyte	Batch Number	Reason	Sample Name
Cotinine	13	AAR	AA97220-01 05104620000950 12 N/A 6 / Day 1 0.1667h SER-1
Cotinine	13	AAR	AA97220-01 05104620000951 12 N/A 7 / Day 1 0.25h SER-1
Cotinine	13	AAR	AA97220-01 05104620000952 12 N/A 8 / Day 1 0.333h SER-1
Cotinine	13	AAR	AA97220-01 05104620000953 12 N/A 9 / Day 1 0.5h SER-1
Cotinine	13	AAR	AA97220-01 05104620000954 12 N/A 10 / Day 1 0.75h SER-1
Cotinine	13	AAR	AA97220-01 05104620000955 12 N/A 11 / Day 1 1h SER-1
Cotinine	13	AAR	AA97220-01 05104620000956 12 N/A 12 / Day 1 1.25h SER-1
Cotinine	13	AAR	AA97220-01 05104620000957 12 N/A 13 / Day 1 1.5h SER-1
Cotinine	13	AAR	AA97220-01 05104620000958 12 N/A 14 / Day 1 2h SER-1
Cotinine	13	AAR	AA97220-01 05104620000959 12 N/A 15 / Day 1 2.5h SER-1
Cotinine	13	AAR	AA97220-01 05104620000960 12 N/A 16 / Day 1 3h SER-1
Cotinine	14	AAR	AA97220-01 05104620000913 12 N/A 1 / Day 1 -0.0333h SER-1
Cotinine	14	AAR	AA97220-01 05104620000929 12 N/A 1 / Day 1 -0.0333h SER-1
Cotinine	14	AAR	AA97220-01 05104620000881 12 N/A 1 / Day 1 -0.0333h SER-1
Cotinine	14	AAR	AA97220-01 05104620000897 12 N/A 1 / Day 1 -0.0333h SER-1
Cotinine	14	AAR	AA97220-01 05104620000914 12 N/A 2 / Day 1 0h SER-1
Cotinine	14	AAR	AA97220-01 05104620000898 12 N/A 2 / Day 1 0h SER-1
Cotinine	14	AAR	AA97220-01 05104620000882 12 N/A 2 / Day 1 0h SER-1
Cotinine	14	AAR	AA97220-01 05104620000930 12 N/A 2 / Day 1 0h SER-1
Cotinine	14	AAR	AA97220-01 05104620000883 12 N/A 3 / Day 1 0.05h SER-1
Cotinine	14	AAR	AA97220-01 05104620000931 12 N/A 3 / Day 1 0.05h SER-1
Cotinine	14	AAR	AA97220-01 05104620000899 12 N/A 3 / Day 1 0.05h SER-1
Cotinine	14	AAR	AA97220-01 05104620000915 12 N/A 3 / Day 1 0.05h SER-1
Cotinine	14	AAR	AA97220-01 05104620000932 12 N/A 4 / Day 1 0.0833h SER-1
Cotinine	14	AAR	AA97220-01 05104620000900 12 N/A 4 / Day 1 0.0833h SER-1
Cotinine	14	AAR	AA97220-01 05104620000916 12 N/A 4 / Day 1 0.0833h SER-1
Cotinine	14	AAR	AA97220-01 05104620000884 12 N/A 4 / Day 1 0.0833h SER-1
Cotinine	14	AAR	AA97220-01 05104620000885 12 N/A 5 / Day 1 0.125h SER-1
Cotinine	14	AAR	AA97220-01 05104620000901 12 N/A 5 / Day 1 0.125h SER-1
Cotinine	14	AAR	AA97220-01 05104620000917 12 N/A 5 / Day 1 0.125h SER-1
Cotinine	14	AAR	AA97220-01 05104620000933 12 N/A 5 / Day 1 0.125h SER-1
Cotinine	14	AAR	AA97220-01 05104620000886 12 N/A 6 / Day 1 0.1667h SER-1
Cotinine	14	AAR	AA97220-01 05104620000934 12 N/A 6 / Day 1 0.1667h SER-1
Cotinine	14	AAR	AA97220-01 05104620000902 12 N/A 6 / Day 1 0.1667h SER-1
Cotinine	14	AAR	AA97220-01 05104620000918 12 N/A 6 / Day 1 0.1667h SER-1
Cotinine	14	AAR	AA97220-01 05104620000935 12 N/A 7 / Day 1 0.25h SER-1
Cotinine	14	AAR	AA97220-01 05104620000919 12 N/A 7 / Day 1 0.25h SER-1
Cotinine	14	AAR	AA97220-01 05104620000903 12 N/A 7 / Day 1 0.25h SER-1
Cotinine	14	AAR	AA97220-01 05104620000887 12 N/A 7 / Day 1 0.25h SER-1
Cotinine	14	AAR	AA97220-01 05104620000936 12 N/A 8 / Day 1 0.333h SER-1
Cotinine	14	AAR	AA97220-01 05104620000888 12 N/A 8 / Day 1 0.333h SER-1
Cotinine	14	AAR	AA97220-01 05104620000904 12 N/A 8 / Day 1 0.333h SER-1
Cotinine	14	AAR	AA97220-01 05104620000920 12 N/A 8 / Day 1 0.333h SER-1

Analyte	Batch Number	Reason	Sample Name
Cotinine	14	AAR	AA97220-01 05104620000937 12 N/A 9 / Day 1 0.5h SER-1
Cotinine	14	AAR	AA97220-01 05104620000921 12 N/A 9 / Day 1 0.5h SER-1
Cotinine	14	AAR	AA97220-01 05104620000905 12 N/A 9 / Day 1 0.5h SER-1
Cotinine	14	AAR	AA97220-01 05104620000889 12 N/A 9 / Day 1 0.5h SER-1
Cotinine	14	AAR	AA97220-01 05104620000938 12 N/A 10 / Day 1 0.75h SER-1
Cotinine	14	AAR	AA97220-01 05104620000922 12 N/A 10 / Day 1 0.75h SER-1
Cotinine	14	AAR	AA97220-01 05104620000890 12 N/A 10 / Day 1 0.75h SER-1
Cotinine	14	AAR	AA97220-01 05104620000906 12 N/A 10 / Day 1 0.75h SER-1
Cotinine	14	AAR	AA97220-01 05104620000891 12 N/A 11 / Day 1 1h SER-1
Cotinine	14	AAR	AA97220-01 05104620000939 12 N/A 11 / Day 1 1h SER-1
Cotinine	14	AAR	AA97220-01 05104620000923 12 N/A 11 / Day 1 1h SER-1
Cotinine	14	AAR	AA97220-01 05104620000907 12 N/A 11 / Day 1 1h SER-1
Cotinine	14	AAR	AA97220-01 05104620000892 12 N/A 12 / Day 1 1.25h SER-1
Cotinine	14	AAR	AA97220-01 05104620000940 12 N/A 12 / Day 1 1.25h SER-1
Cotinine	14	AAR	AA97220-01 05104620000924 12 N/A 12 / Day 1 1.25h SER-1
Cotinine	14	AAR	AA97220-01 05104620000908 12 N/A 12 / Day 1 1.25h SER-1
Cotinine	14	AAR	AA97220-01 05104620000925 12 N/A 13 / Day 1 1.5h SER-1
Cotinine	14	AAR	AA97220-01 05104620000909 12 N/A 13 / Day 1 1.5h SER-1
Cotinine	14	AAR	AA97220-01 05104620000893 12 N/A 13 / Day 1 1.5h SER-1
Cotinine	14	AAR	AA97220-01 05104620000941 12 N/A 13 / Day 1 1.5h SER-1
Cotinine	14	AAR	AA97220-01 05104620000942 12 N/A 14 / Day 1 2h SER-1
Cotinine	14	AAR	AA97220-01 05104620000894 12 N/A 14 / Day 1 2h SER-1
Cotinine	14	AAR	AA97220-01 05104620000926 12 N/A 14 / Day 1 2h SER-1
Cotinine	14	AAR	AA97220-01 05104620000910 12 N/A 14 / Day 1 2h SER-1
Cotinine	14	AAR	AA97220-01 05104620000895 12 N/A 15 / Day 1 2.5h SER-1
Cotinine	14	AAR	AA97220-01 05104620000943 12 N/A 15 / Day 1 2.5h SER-1
Cotinine	14	AAR	AA97220-01 05104620000927 12 N/A 15 / Day 1 2.5h SER-1
Cotinine	14	AAR	AA97220-01 05104620000911 12 N/A 15 / Day 1 2.5h SER-1
Cotinine	14	AAR	AA97220-01 05104620000944 12 N/A 16 / Day 1 3h SER-1
Cotinine	14	AAR	AA97220-01 05104620000896 12 N/A 16 / Day 1 3h SER-1
Cotinine	14	AAR	AA97220-01 05104620000928 12 N/A 16 / Day 1 3h SER-1
Cotinine	14	AAR	AA97220-01 05104620000912 12 N/A 16 / Day 1 3h SER-1
Cotinine	15	Fail	AA97220-01 05104620000993 13 N/A 1 / Day 1 -0.0333h SER-1
Cotinine	15	Fail	AA97220-01 05104620001025 13 N/A 1 / Day 1 -0.0333h SER-1
Cotinine	15	AAR/Fail	AA97220-01 05104620001009 13 N/A 1 / Day 1 -0.0333h SER-1
Cotinine	15	Fail	AA97220-01 05104620000977 13 N/A 1 / Day 1 -0.0333h SER-1
Cotinine	15	Fail	AA97220-01 05104620001010 13 N/A 2 / Day 1 0h SER-1
Cotinine	15	Fail	AA97220-01 05104620000994 13 N/A 2 / Day 1 0h SER-1
Cotinine	15	Fail	AA97220-01 05104620000978 13 N/A 2 / Day 1 0h SER-1
Cotinine	15	Fail	AA97220-01 05104620001026 13 N/A 2 / Day 1 0h SER-1
Cotinine	15	Fail	AA97220-01 05104620001027 13 N/A 3 / Day 1 0.05h SER-1
Cotinine	15	Fail	AA97220-01 05104620000979 13 N/A 3 / Day 1 0.05h SER-1
Cotinine	15	AAR/Fail	AA97220-01 05104620001011 13 N/A 3 / Day 1 0.05h SER-1

Analyte	Batch Number	Reason	Sample Name
Cotinine	15	Fail	AA97220-01 05104620000995 13 N/A 3 / Day 1 0.05h SER-1
Cotinine	15	Fail	AA97220-01 05104620000980 13 N/A 4 / Day 1 0.0833h SER-1
Cotinine	15	Fail	AA97220-01 05104620001028 13 N/A 4 / Day 1 0.0833h SER-1
Cotinine	15	Fail	AA97220-01 05104620000996 13 N/A 4 / Day 1 0.0833h SER-1
Cotinine	15	Fail	AA97220-01 05104620001012 13 N/A 4 / Day 1 0.0833h SER-1
Cotinine	15	Fail	AA97220-01 05104620001013 13 N/A 5 / Day 1 0.125h SER-1
Cotinine	15	Fail	AA97220-01 05104620000981 13 N/A 5 / Day 1 0.125h SER-1
Cotinine	15	Fail	AA97220-01 05104620000997 13 N/A 5 / Day 1 0.125h SER-1
Cotinine	15	Fail	AA97220-01 05104620001029 13 N/A 5 / Day 1 0.125h SER-1
Cotinine	15	Fail	AA97220-01 05104620000982 13 N/A 6 / Day 1 0.1667h SER-1
Cotinine	15	ISA/Fail	AA97220-01 05104620001030 13 N/A 6 / Day 1 0.1667h SER-1
Cotinine	15	Fail	AA97220-01 05104620000998 13 N/A 6 / Day 1 0.1667h SER-1
Cotinine	15	Fail	AA97220-01 05104620001014 13 N/A 6 / Day 1 0.1667h SER-1
Cotinine	15	Fail	AA97220-01 05104620001031 13 N/A 7 / Day 1 0.25h SER-1
Cotinine	15	Fail	AA97220-01 05104620001015 13 N/A 7 / Day 1 0.25h SER-1
Cotinine	15	Fail	AA97220-01 05104620000983 13 N/A 7 / Day 1 0.25h SER-1
Cotinine	15	Fail	AA97220-01 05104620000999 13 N/A 7 / Day 1 0.25h SER-1
Cotinine	15	Fail	AA97220-01 05104620001032 13 N/A 8 / Day 1 0.333h SER-1
Cotinine	15	Fail	AA97220-01 05104620001000 13 N/A 8 / Day 1 0.333h SER-1
Cotinine	15	Fail	AA97220-01 05104620000984 13 N/A 8 / Day 1 0.333h SER-1
Cotinine	15	Fail	AA97220-01 05104620001016 13 N/A 8 / Day 1 0.333h SER-1
Cotinine	15	Fail	AA97220-01 05104620001033 13 N/A 9 / Day 1 0.5h SER-1
Cotinine	15	Fail	AA97220-01 05104620001017 13 N/A 9 / Day 1 0.5h SER-1
Cotinine	15	Fail	AA97220-01 05104620000985 13 N/A 9 / Day 1 0.5h SER-1
Cotinine	15	Fail	AA97220-01 05104620001001 13 N/A 9 / Day 1 0.5h SER-1
Cotinine	15	Fail	AA97220-01 05104620000986 13 N/A 10 / Day 1 0.75h SER-1
Cotinine	15	Fail	AA97220-01 05104620001034 13 N/A 10 / Day 1 0.75h SER-1
Cotinine	15	Fail	AA97220-01 05104620001018 13 N/A 10 / Day 1 0.75h SER-1
Cotinine	15	Fail	AA97220-01 05104620001002 13 N/A 10 / Day 1 0.75h SER-1
Cotinine	15	Fail	AA97220-01 05104620001035 13 N/A 11 / Day 1 1h SER-1
Cotinine	15	Fail	AA97220-01 05104620001003 13 N/A 11 / Day 1 1h SER-1
Cotinine	15	Fail	AA97220-01 05104620001019 13 N/A 11 / Day 1 1h SER-1
Cotinine	15	Fail	AA97220-01 05104620000987 13 N/A 11 / Day 1 1h SER-1
Cotinine	15	Fail	AA97220-01 05104620001036 13 N/A 12 / Day 1 1.25h SER-1
Cotinine	15	Fail	AA97220-01 05104620000988 13 N/A 12 / Day 1 1.25h SER-1
Cotinine	15	Fail	AA97220-01 05104620001020 13 N/A 12 / Day 1 1.25h SER-1
Cotinine	15	Fail	AA97220-01 05104620001004 13 N/A 12 / Day 1 1.25h SER-1
Cotinine	15	Fail	AA97220-01 05104620001021 13 N/A 13 / Day 1 1.5h SER-1
Cotinine	15	Fail	AA97220-01 05104620000989 13 N/A 13 / Day 1 1.5h SER-1
Cotinine	15	Fail	AA97220-01 05104620001037 13 N/A 13 / Day 1 1.5h SER-1
Cotinine	15	Fail	AA97220-01 05104620001005 13 N/A 13 / Day 1 1.5h SER-1
Cotinine	15	Fail	AA97220-01 05104620001022 13 N/A 14 / Day 1 2h SER-1
Cotinine	15	Fail	AA97220-01 05104620000990 13 N/A 14 / Day 1 2h SER-1

Analyte	Batch Number	Reason	Sample Name
Cotinine	15	Fail	AA97220-01 05104620001006 13 N/A 14 / Day 1 2h SER-1
Cotinine	15	Fail	AA97220-01 05104620001038 13 N/A 14 / Day 1 2h SER-1
Cotinine	15	Fail	AA97220-01 05104620001023 13 N/A 15 / Day 1 2.5h SER-1
Cotinine	15	Fail	AA97220-01 05104620001007 13 N/A 15 / Day 1 2.5h SER-1
Cotinine	15	Fail	AA97220-01 05104620000991 13 N/A 15 / Day 1 2.5h SER-1
Cotinine	15	Fail	AA97220-01 05104620001039 13 N/A 15 / Day 1 2.5h SER-1
Cotinine	15	Fail	AA97220-01 05104620001008 13 N/A 16 / Day 1 3h SER-1
Cotinine	15	Fail	AA97220-01 05104620000992 13 N/A 16 / Day 1 3h SER-1
Cotinine	15	Fail	AA97220-01 05104620001024 13 N/A 16 / Day 1 3h SER-1
Cotinine	15	Fail	AA97220-01 05104620001040 13 N/A 16 / Day 1 3h SER-1
Cotinine	16	UISR	AA97220-01 05104620000971 13 N/A 11 / Day 1 1h SER-1
Cotinine	16	AAR	AA97220-01 05104620001105 14 N/A 1 / Day 1 -0.0333h SER-1
Cotinine	16	AAR	AA97220-01 05104620001073 14 N/A 1 / Day 1 -0.0333h SER-1
Cotinine	16	AAR	AA97220-01 05104620001089 14 N/A 1 / Day 1 -0.0333h SER-1
Cotinine	16	AAR	AA97220-01 05104620001090 14 N/A 2 / Day 1 0h SER-1
Cotinine	16	AAR	AA97220-01 05104620001106 14 N/A 2 / Day 1 0h SER-1
Cotinine	16	AAR	AA97220-01 05104620001074 14 N/A 2 / Day 1 0h SER-1
Cotinine	16	AAR	AA97220-01 05104620001091 14 N/A 3 / Day 1 0.05h SER-1
Cotinine	16	AAR	AA97220-01 05104620001107 14 N/A 3 / Day 1 0.05h SER-1
Cotinine	16	AAR	AA97220-01 05104620001075 14 N/A 3 / Day 1 0.05h SER-1
Cotinine	16	AAR	AA97220-01 05104620001108 14 N/A 4 / Day 1 0.0833h SER-1
Cotinine	16	AAR	AA97220-01 05104620001076 14 N/A 4 / Day 1 0.0833h SER-1
Cotinine	16	AAR	AA97220-01 05104620001092 14 N/A 4 / Day 1 0.0833h SER-1
Cotinine	16	AAR	AA97220-01 05104620001093 14 N/A 5 / Day 1 0.125h SER-1
Cotinine	16	AAR	AA97220-01 05104620001109 14 N/A 5 / Day 1 0.125h SER-1
Cotinine	16	AAR	AA97220-01 05104620001077 14 N/A 5 / Day 1 0.125h SER-1
Cotinine	16	AAR	AA97220-01 05104620001078 14 N/A 6 / Day 1 0.1667h SER-1
Cotinine	16	AAR	AA97220-01 05104620001110 14 N/A 6 / Day 1 0.1667h SER-1
Cotinine	16	AAR	AA97220-01 05104620001094 14 N/A 6 / Day 1 0.1667h SER-1
Cotinine	16	AAR	AA97220-01 05104620001111 14 N/A 7 / Day 1 0.25h SER-1
Cotinine	16	AAR	AA97220-01 05104620001079 14 N/A 7 / Day 1 0.25h SER-1
Cotinine	16	AAR	AA97220-01 05104620001095 14 N/A 7 / Day 1 0.25h SER-1
Cotinine	16	AAR	AA97220-01 05104620001080 14 N/A 8 / Day 1 0.333h SER-1
Cotinine	16	AAR	AA97220-01 05104620001096 14 N/A 8 / Day 1 0.333h SER-1
Cotinine	16	AAR	AA97220-01 05104620001112 14 N/A 8 / Day 1 0.333h SER-1
Cotinine	16	AAR	AA97220-01 05104620001081 14 N/A 9 / Day 1 0.5h SER-1
Cotinine	16	AAR	AA97220-01 05104620001113 14 N/A 9 / Day 1 0.5h SER-1
Cotinine	16	AAR	AA97220-01 05104620001097 14 N/A 9 / Day 1 0.5h SER-1
Cotinine	16	AAR	AA97220-01 05104620001114 14 N/A 10 / Day 1 0.75h SER-1
Cotinine	16	AAR	AA97220-01 05104620001082 14 N/A 10 / Day 1 0.75h SER-1
Cotinine	16	AAR	AA97220-01 05104620001098 14 N/A 10 / Day 1 0.75h SER-1
Cotinine	16	AAR	AA97220-01 05104620001099 14 N/A 11 / Day 1 1h SER-1
Cotinine	16	AAR	AA97220-01 05104620001115 14 N/A 11 / Day 1 1h SER-1

Analyte	Batch Number	Reason	Sample Name
Cotinine	16	AAR	AA97220-01 05104620001083 14 N/A 11 / Day 1 1h SER-1
Cotinine	16	AAR	AA97220-01 05104620001116 14 N/A 12 / Day 1 1.25h SER-1
Cotinine	16	AAR	AA97220-01 05104620001084 14 N/A 12 / Day 1 1.25h SER-1
Cotinine	16	AAR	AA97220-01 05104620001101 14 N/A 13 / Day 1 1.5h SER-1
Cotinine	16	AAR	AA97220-01 05104620001117 14 N/A 13 / Day 1 1.5h SER-1
Cotinine	16	AAR	AA97220-01 05104620001085 14 N/A 13 / Day 1 1.5h SER-1
Cotinine	16	AAR	AA97220-01 05104620001118 14 N/A 14 / Day 1 2h SER-1
Cotinine	16	AAR	AA97220-01 05104620001086 14 N/A 14 / Day 1 2h SER-1
Cotinine	16	AAR	AA97220-01 05104620001102 14 N/A 14 / Day 1 2h SER-1
Cotinine	16	AAR	AA97220-01 05104620001119 14 N/A 15 / Day 1 2.5h SER-1
Cotinine	16	UISR	AA97220-01 05104620001103 14 N/A 15 / Day 1 2.5h SER-1
Cotinine	16	UISR	AA97220-01 05104620001087 14 N/A 15 / Day 1 2.5h SER-1
Cotinine	16	AAR	AA97220-01 05104620001104 14 N/A 16 / Day 1 3h SER-1
Cotinine	16	UISR	AA97220-01 05104620001120 14 N/A 16 / Day 1 3h SER-1
Cotinine	16	UISR	AA97220-01 05104620001088 14 N/A 16 / Day 1 3h SER-1
Cotinine	17	AAR	AA97220-01 05104620001057 14 N/A 1 / Day 1 -0.0333h SER-1
Cotinine	17	AAR	AA97220-01 05104620001041 14 N/A 1 / Day 1 -0.0333h SER-1
Cotinine	17	AAR	AA97220-01 05104620001042 14 N/A 2 / Day 1 0h SER-1
Cotinine	17	AAR	AA97220-01 05104620001043 14 N/A 3 / Day 1 0.05h SER-1
Cotinine	17	AAR	AA97220-01 05104620001044 14 N/A 4 / Day 1 0.0833h SER-1
Cotinine	17	AAR	AA97220-01 05104620001060 14 N/A 4 / Day 1 0.0833h SER-1
Cotinine	17	AAR	AA97220-01 05104620001045 14 N/A 5 / Day 1 0.125h SER-1
Cotinine	17	AAR	AA97220-01 05104620001046 14 N/A 6 / Day 1 0.1667h SER-1
Cotinine	17	AAR	AA97220-01 05104620001047 14 N/A 7 / Day 1 0.25h SER-1
Cotinine	17	AAR	AA97220-01 05104620001048 14 N/A 8 / Day 1 0.333h SER-1
Cotinine	17	AAR	AA97220-01 05104620001064 14 N/A 8 / Day 1 0.333h SER-1
Cotinine	17	AAR	AA97220-01 05104620001049 14 N/A 9 / Day 1 0.5h SER-1
Cotinine	17	AAR	AA97220-01 05104620001066 14 N/A 10 / Day 1 0.75h SER-1
Cotinine	17	AAR	AA97220-01 05104620001050 14 N/A 10 / Day 1 0.75h SER-1
Cotinine	17	AAR	AA97220-01 05104620001051 14 N/A 11 / Day 1 1h SER-1
Cotinine	17	AAR	AA97220-01 05104620001052 14 N/A 12 / Day 1 1.25h SER-1
Cotinine	17	AAR	AA97220-01 05104620001053 14 N/A 13 / Day 1 1.5h SER-1
Cotinine	17	AAR	AA97220-01 05104620001054 14 N/A 14 / Day 1 2h SER-1
Cotinine	17	AAR	AA97220-01 05104620001070 14 N/A 14 / Day 1 2h SER-1
Cotinine	17	AAR	AA97220-01 05104620001055 14 N/A 15 / Day 1 2.5h SER-1
Cotinine	17	AAR	AA97220-01 05104620001056 14 N/A 16 / Day 1 3h SER-1
Cotinine	17	AAR	AA97220-01 05104620001185 15 N/A 1 / Day 1 -0.0333h SER-1
Cotinine	17	AAR	AA97220-01 05104620001169 15 N/A 1 / Day 1 -0.0333h SER-1
Cotinine	17	AAR	AA97220-01 05104620001170 15 N/A 2 / Day 1 0h SER-1
Cotinine	17	AAR	AA97220-01 05104620001171 15 N/A 3 / Day 1 0.05h SER-1
Cotinine	17	AAR	AA97220-01 05104620001172 15 N/A 4 / Day 1 0.0833h SER-1
Cotinine	17	AAR	AA97220-01 05104620001173 15 N/A 5 / Day 1 0.125h SER-1
Cotinine	17	AAR	AA97220-01 05104620001189 15 N/A 5 / Day 1 0.125h SER-1

Analyte	Batch Number	Reason	Sample Name
Cotinine	17	AAR	AA97220-01 05104620001174 15 N/A 6 / Day 1 0.1667h SER-1
Cotinine	17	AAR	AA97220-01 05104620001190 15 N/A 6 / Day 1 0.1667h SER-1
Cotinine	17	AAR	AA97220-01 05104620001191 15 N/A 7 / Day 1 0.25h SER-1
Cotinine	17	AAR	AA97220-01 05104620001175 15 N/A 7 / Day 1 0.25h SER-1
Cotinine	17	AAR	AA97220-01 05104620001176 15 N/A 8 / Day 1 0.333h SER-1
Cotinine	17	AAR	AA97220-01 05104620001192 15 N/A 8 / Day 1 0.333h SER-1
Cotinine	17	AAR	AA97220-01 05104620001177 15 N/A 9 / Day 1 0.5h SER-1
Cotinine	17	AAR	AA97220-01 05104620001193 15 N/A 9 / Day 1 0.5h SER-1
Cotinine	17	AAR	AA97220-01 05104620001178 15 N/A 10 / Day 1 0.75h SER-1
Cotinine	17	AAR	AA97220-01 05104620001194 15 N/A 10 / Day 1 0.75h SER-1
Cotinine	17	AAR	AA97220-01 05104620001179 15 N/A 11 / Day 1 1h SER-1
Cotinine	17	AAR	AA97220-01 05104620001195 15 N/A 11 / Day 1 1h SER-1
Cotinine	17	AAR	AA97220-01 05104620001180 15 N/A 12 / Day 1 1.25h SER-1
Cotinine	17	AAR	AA97220-01 05104620001196 15 N/A 12 / Day 1 1.25h SER-1
Cotinine	17	AAR	AA97220-01 05104620001181 15 N/A 13 / Day 1 1.5h SER-1
Cotinine	17	AAR	AA97220-01 05104620001197 15 N/A 13 / Day 1 1.5h SER-1
Cotinine	17	AAR	AA97220-01 05104620001198 15 N/A 14 / Day 1 2h SER-1
Cotinine	17	AAR	AA97220-01 05104620001182 15 N/A 14 / Day 1 2h SER-1
Cotinine	17	AAR	AA97220-01 05104620001183 15 N/A 15 / Day 1 2.5h SER-1
Cotinine	17	AAR	AA97220-01 05104620001199 15 N/A 15 / Day 1 2.5h SER-1
Cotinine	17	AAR	AA97220-01 05104620001200 15 N/A 16 / Day 1 3h SER-1
Cotinine	17	AAR	AA97220-01 05104620001184 15 N/A 16 / Day 1 3h SER-1
Cotinine	18	AAR	AA97220-01 05104620001137 15 N/A 1 / Day 1 -0.0333h SER-1
Cotinine	18	AAR	AA97220-01 05104620001124 15 N/A 4 / Day 1 0.0833h SER-1
Cotinine	18	AAR	AA97220-01 05104620001127 15 N/A 7 / Day 1 0.25h SER-1
Cotinine	18	AAR	AA97220-01 05104620001128 15 N/A 8 / Day 1 0.333h SER-1
Cotinine	18	AAR	AA97220-01 05104620001162 15 N/A 10 / Day 1 0.75h SER-1
Cotinine	18	AAR	AA97220-01 05104620001130 15 N/A 10 / Day 1 0.75h SER-1
Cotinine	18	AAR	AA97220-01 05104620001131 15 N/A 11 / Day 1 1h SER-1
Cotinine	18	AAR	AA97220-01 05104620001147 15 N/A 11 / Day 1 1h SER-1
Cotinine	18	AAR	AA97220-01 05104620001132 15 N/A 12 / Day 1 1.25h SER-1
Cotinine	18	UI SR	AA97220-01 05104620001166 15 N/A 14 / Day 1 2h SER-1
Cotinine	18	AAR	AA97220-01 05104620001134 15 N/A 14 / Day 1 2h SER-1
Cotinine	18	UI SR	AA97220-01 05104620001267 16 N/A 3 / Day 1 0.05h SER-1
Cotinine	18	UI SR	AA97220-01 05104620001273 16 N/A 9 / Day 1 0.5h SER-1
Cotinine	18	AAR	AA97220-01 05104620001277 16 N/A 13 / Day 1 1.5h SER-1
Cotinine	19	AAR	AA97220-01 05104620001201 16 N/A 1 / Day 1 -0.0333h SER-1
Cotinine	19	AAR	AA97220-01 05104620001202 16 N/A 2 / Day 1 0h SER-1
Cotinine	19	AAR	AA97220-01 05104620001203 16 N/A 3 / Day 1 0.05h SER-1
Cotinine	19	AAR	AA97220-01 05104620001204 16 N/A 4 / Day 1 0.0833h SER-1
Cotinine	19	AAR	AA97220-01 05104620001205 16 N/A 5 / Day 1 0.125h SER-1
Cotinine	19	AAR	AA97220-01 05104620001206 16 N/A 6 / Day 1 0.1667h SER-1
Cotinine	19	AAR	AA97220-01 05104620001207 16 N/A 7 / Day 1 0.25h SER-1

Analyte	Batch Number	Reason	Sample Name
Cotinine	19	AAR	AA97220-01 05104620001208 16 N/A 8 / Day 1 0.333h SER-1
Cotinine	19	AAR	AA97220-01 05104620001209 16 N/A 9 / Day 1 0.5h SER-1
Cotinine	19	AAR	AA97220-01 05104620001210 16 N/A 10 / Day 1 0.75h SER-1
Cotinine	19	AAR	AA97220-01 05104620001211 16 N/A 11 / Day 1 1h SER-1
Cotinine	19	AAR	AA97220-01 05104620001212 16 N/A 12 / Day 1 1.25h SER-1
Cotinine	19	AAR	AA97220-01 05104620001213 16 N/A 13 / Day 1 1.5h SER-1
Cotinine	19	AAR	AA97220-01 05104620001214 16 N/A 14 / Day 1 2h SER-1
Cotinine	19	AAR	AA97220-01 05104620001215 16 N/A 15 / Day 1 2.5h SER-1
Cotinine	20	AAR	AA97220-01 05104620001345 17 N/A 1 / Day 1 -0.0333h SER-1
Cotinine	20	AAR	AA97220-01 05104620001313 17 N/A 1 / Day 1 -0.0333h SER-1
Cotinine	20	AAR	AA97220-01 05104620001297 17 N/A 1 / Day 1 -0.0333h SER-1
Cotinine	20	AAR	AA97220-01 05104620001298 17 N/A 2 / Day 1 0h SER-1
Cotinine	20	AAR	AA97220-01 05104620001346 17 N/A 2 / Day 1 0h SER-1
Cotinine	20	AAR	AA97220-01 05104620001314 17 N/A 2 / Day 1 0h SER-1
Cotinine	20	AAR	AA97220-01 05104620001315 17 N/A 3 / Day 1 0.05h SER-1
Cotinine	20	AAR	AA97220-01 05104620001299 17 N/A 3 / Day 1 0.05h SER-1
Cotinine	20	AAR	AA97220-01 05104620001347 17 N/A 3 / Day 1 0.05h SER-1
Cotinine	20	AAR	AA97220-01 05104620001316 17 N/A 4 / Day 1 0.0833h SER-1
Cotinine	20	AAR	AA97220-01 05104620001348 17 N/A 4 / Day 1 0.0833h SER-1
Cotinine	20	AAR	AA97220-01 05104620001300 17 N/A 4 / Day 1 0.0833h SER-1
Cotinine	20	AAR	AA97220-01 05104620001349 17 N/A 5 / Day 1 0.125h SER-1
Cotinine	20	AAR	AA97220-01 05104620001317 17 N/A 5 / Day 1 0.125h SER-1
Cotinine	20	AAR	AA97220-01 05104620001301 17 N/A 5 / Day 1 0.125h SER-1
Cotinine	20	AAR	AA97220-01 05104620001350 17 N/A 6 / Day 1 0.1667h SER-1
Cotinine	20	AAR	AA97220-01 05104620001318 17 N/A 6 / Day 1 0.1667h SER-1
Cotinine	20	AAR	AA97220-01 05104620001302 17 N/A 6 / Day 1 0.1667h SER-1
Cotinine	20	AAR	AA97220-01 05104620001351 17 N/A 7 / Day 1 0.25h SER-1
Cotinine	20	AAR	AA97220-01 05104620001303 17 N/A 7 / Day 1 0.25h SER-1
Cotinine	20	AAR	AA97220-01 05104620001319 17 N/A 7 / Day 1 0.25h SER-1
Cotinine	20	AAR	AA97220-01 05104620001304 17 N/A 8 / Day 1 0.333h SER-1
Cotinine	20	AAR	AA97220-01 05104620001352 17 N/A 8 / Day 1 0.333h SER-1
Cotinine	20	AAR	AA97220-01 05104620001320 17 N/A 8 / Day 1 0.333h SER-1
Cotinine	20	AAR	AA97220-01 05104620001321 17 N/A 9 / Day 1 0.5h SER-1
Cotinine	20	AAR	AA97220-01 05104620001353 17 N/A 9 / Day 1 0.5h SER-1
Cotinine	20	AAR	AA97220-01 05104620001305 17 N/A 9 / Day 1 0.5h SER-1
Cotinine	20	AAR	AA97220-01 05104620001354 17 N/A 10 / Day 1 0.75h SER-1
Cotinine	20	AAR	AA97220-01 05104620001306 17 N/A 10 / Day 1 0.75h SER-1
Cotinine	20	AAR	AA97220-01 05104620001322 17 N/A 10 / Day 1 0.75h SER-1
Cotinine	20	AAR	AA97220-01 05104620001307 17 N/A 11 / Day 1 1h SER-1
Cotinine	20	AAR	AA97220-01 05104620001323 17 N/A 11 / Day 1 1h SER-1
Cotinine	20	AAR	AA97220-01 05104620001355 17 N/A 11 / Day 1 1h SER-1
Cotinine	20	AAR	AA97220-01 05104620001308 17 N/A 12 / Day 1 1.25h SER-1
Cotinine	20	AAR	AA97220-01 05104620001356 17 N/A 12 / Day 1 1.25h SER-1

Analyte	Batch Number	Reason	Sample Name
Cotinine	20	AAR	AA97220-01 05104620001324 17 N/A 12 / Day 1 1.25h SER-1
Cotinine	20	AAR	AA97220-01 05104620001357 17 N/A 13 / Day 1 1.5h SER-1
Cotinine	20	AAR	AA97220-01 05104620001309 17 N/A 13 / Day 1 1.5h SER-1
Cotinine	20	AAR	AA97220-01 05104620001325 17 N/A 13 / Day 1 1.5h SER-1
Cotinine	20	AAR	AA97220-01 05104620001326 17 N/A 14 / Day 1 2h SER-1
Cotinine	20	AAR	AA97220-01 05104620001310 17 N/A 14 / Day 1 2h SER-1
Cotinine	20	AAR	AA97220-01 05104620001358 17 N/A 14 / Day 1 2h SER-1
Cotinine	20	AAR	AA97220-01 05104620001359 17 N/A 15 / Day 1 2.5h SER-1
Cotinine	20	AAR	AA97220-01 05104620001327 17 N/A 15 / Day 1 2.5h SER-1
Cotinine	20	AAR	AA97220-01 05104620001311 17 N/A 15 / Day 1 2.5h SER-1
Cotinine	20	AAR	AA97220-01 05104620001328 17 N/A 16 / Day 1 3h SER-1
Cotinine	20	AAR	AA97220-01 05104620001312 17 N/A 16 / Day 1 3h SER-1
Cotinine	20	AAR	AA97220-01 05104620001360 17 N/A 16 / Day 1 3h SER-1
Cotinine	23	AAR	AA97220-01 05104620000705 09 N/A 1 / Day 1 -0.0333h SER-1
Cotinine	30	AAR	AA97220-01 05104620001009 13 N/A 1 / Day 1 -0.0333h SER-1
Cotinine	30	AAR	AA97220-01 05104620001010 13 N/A 2 / Day 1 0h SER-1
Cotinine	30	AAR	AA97220-01 05104620001011 13 N/A 3 / Day 1 0.05h SER-1
Cotinine	30	AAR	AA97220-01 05104620001012 13 N/A 4 / Day 1 0.0833h SER-1
Cotinine	30	AAR	AA97220-01 05104620001014 13 N/A 6 / Day 1 0.1667h SER-1
Cotinine	33	AAR	AA97220-01 05104620001281 17 N/A 1 / Day 1 -0.0333h SER-1
Cotinine	33	AAR	AA97220-01 05104620001282 17 N/A 2 / Day 1 0h SER-1
Cotinine	33	AAR	AA97220-01 05104620001283 17 N/A 3 / Day 1 0.05h SER-1
Cotinine	33	AAR	AA97220-01 05104620001284 17 N/A 4 / Day 1 0.0833h SER-1
Cotinine	33	AAR	AA97220-01 05104620001285 17 N/A 5 / Day 1 0.125h SER-1
Cotinine	33	AAR	AA97220-01 05104620001286 17 N/A 6 / Day 1 0.1667h SER-1
Cotinine	33	AAR	AA97220-01 05104620001287 17 N/A 7 / Day 1 0.25h SER-1
Cotinine	33	AAR	AA97220-01 05104620001288 17 N/A 8 / Day 1 0.333h SER-1
Cotinine	33	AAR	AA97220-01 05104620001289 17 N/A 9 / Day 1 0.5h SER-1
Cotinine	33	AAR	AA97220-01 05104620001290 17 N/A 10 / Day 1 0.75h SER-1
Cotinine	33	AAR	AA97220-01 05104620001291 17 N/A 11 / Day 1 1h SER-1
Cotinine	33	AAR	AA97220-01 05104620001292 17 N/A 12 / Day 1 1.25h SER-1
Cotinine	33	AAR	AA97220-01 05104620001293 17 N/A 13 / Day 1 1.5h SER-1
Cotinine	33	AAR	AA97220-01 05104620001294 17 N/A 14 / Day 1 2h SER-1
Cotinine	33	AAR	AA97220-01 05104620001295 17 N/A 15 / Day 1 2.5h SER-1
Cotinine	33	AAR	AA97220-01 05104620001296 17 N/A 16 / Day 1 3h SER-1

Total Number of Reassays for Analytical Reasons: 762

Table 7. Incurred Sample Reproducibility Samples

Subject	Visit	Time Point	Analyte	Units	Original Value	Reassay Value	Mean Value	% Difference	Reproducible?	Event?	% of Passing ISR Samples
01	5	30 min	Nicotine	ng/mL	4.49	3.79	4.14	16.91	Pass	No	95.9
01	5	180 min	Nicotine	ng/mL	1.82	1.77	1.80	2.78	Pass	No	
01	4	180 min	Nicotine	ng/mL	1.05	0.985	1.02	6.37	Pass	No	
01	3	180 min	Nicotine	ng/mL	0.949	0.831	0.890	13.26	Pass	No	
01	2	20 min	Nicotine	ng/mL	1.27	1.30	1.29	2.33	Pass	No	
01	1	7.5 min	Nicotine	ng/mL	21.9	19.7	20.8	10.58	Pass	No	
02	5	20 min	Nicotine	ng/mL	1.48	1.42	1.45	4.14	Pass	No	95.9
02	5	180 min	Nicotine	ng/mL	0.923	0.936	0.930	1.40	Pass	No	
02	4	180 min	Nicotine	ng/mL	2.45	2.39	2.42	2.48	Pass	No	
02	3	180 min	Nicotine	ng/mL	0.942	0.932	0.937	1.07	Pass	No	
02	2	180 min	Nicotine	ng/mL	0.767	0.696	0.732	9.70	Pass	No	
02	1	180 min	Nicotine	ng/mL	1.90	1.77	1.84	7.07	Pass	No	
03	4	7.5 min	Nicotine	ng/mL	3.03	3.04	3.04	0.33	Pass	No	95.9
03	4	180 min	Nicotine	ng/mL	2.88	3.41	3.15	16.83	Pass	No	
03	3	180 min	Nicotine	ng/mL	3.56	4.06	3.81	13.12	Pass	No	
03	1	15 min	Nicotine	ng/mL	16.2	16.6	16.4	2.44	Pass	No	
03	1	180 min	Nicotine	ng/mL	7.00	7.04	7.02	0.57	Pass	No	
04	5	10 min	Nicotine	ng/mL	3.55	3.47	3.51	2.28	Pass	No	
04	5	180 min	Nicotine	ng/mL	0.778	0.632	0.705	20.71	Fail	No	95.9
04	4	20 min	Nicotine	ng/mL	4.48	4.07	4.28	9.58	Pass	No	

Subject	Visit	Time Point	Analyte	Units	Original Value	Reassay Value	Mean Value	% Difference	Reproducible?	Event?	% of Passing ISR Samples
04	4	180 min	Nicotine	ng/mL	0.891	0.872	0.882	2.15	Pass	No	
04	2	30 min	Nicotine	ng/mL	7.16	6.58	6.87	8.44	Pass	No	
04	2	180 min	Nicotine	ng/mL	1.99	1.92	1.96	3.57	Pass	No	
04	1	5 min	Nicotine	ng/mL	37.7	41.9	39.8	10.55	Pass	No	
05	5	45 min	Nicotine	ng/mL	3.12	3.16	3.14	1.27	Pass	No	
05	5	180 min	Nicotine	ng/mL	1.87	1.82	1.85	2.70	Pass	No	
05	3	30 min	Nicotine	ng/mL	2.49	2.37	2.43	4.94	Pass	No	
05	3	180 min	Nicotine	ng/mL	1.30	1.26	1.28	3.13	Pass	No	
05	2	10 min	Nicotine	ng/mL	3.79	3.64	3.72	4.03	Pass	No	
05	2	180 min	Nicotine	ng/mL	1.77	1.83	1.80	3.33	Pass	No	
06	5	45 min	Nicotine	ng/mL	1.44	1.39	1.42	3.52	Pass	No	
06	5	150 min	Nicotine	ng/mL	0.626	0.784	0.705	22.41	Fail	No	
06	2	180 min	Nicotine	ng/mL	0.763	0.814	0.789	6.46	Pass	No	
07	1	10 min	Nicotine	ng/mL	10.1	9.62	9.86	4.87	Pass	No	
07	1	180 min	Nicotine	ng/mL	2.32	2.36	2.34	1.71	Pass	No	
10	5	30 min	Nicotine	ng/mL	4.93	4.74	4.84	3.93	Pass	No	
10	5	180 min	Nicotine	ng/mL	1.65	1.83	1.74	10.34	Pass	No	
10	4	45 min	Nicotine	ng/mL	4.16	4.51	4.34	8.06	Pass	No	
11	3	20 min	Nicotine	ng/mL	2.14	1.99	2.07	7.25	Pass	No	
11	2	90 min	Nicotine	ng/mL	1.90	1.79	1.85	5.95	Pass	No	
11	1	180 min	Nicotine	ng/mL	2.45	2.56	2.51	4.38	Pass	No	
12	5	45 min	Nicotine	ng/mL	19.2	19.2	19.2	0.00	Pass	No	
12	5	180 min	Nicotine	ng/mL	9.23	9.66	9.45	4.55	Pass	No	

Subject	Visit	Time Point	Analyte	Units	Original Value	Reassay Value	Mean Value	% Difference	Reproducible?	Event?	% of Passing ISR Samples
12	4	180 min	Nicotine	ng/mL	4.98	5.30	5.14	6.23	Pass	No	
12	3	180 min	Nicotine	ng/mL	4.11	4.50	4.31	9.05	Pass	No	
12	2	20 min	Nicotine	ng/mL	5.06	5.44	5.25	7.24	Pass	No	
12	2	180 min	Nicotine	ng/mL	2.63	2.59	2.61	1.53	Pass	No	
12	1	5 min	Nicotine	ng/mL	39.3	39.9	39.6	1.52	Pass	No	
13	5	45 min	Nicotine	ng/mL	2.05	2.11	2.08	2.88	Pass	No	
13	4	15 min	Nicotine	ng/mL	1.72	1.79	1.76	3.98	Pass	No	
13	4	180 min	Nicotine	ng/mL	0.874	0.864	0.869	1.15	Pass	No	
13	3	30 min	Nicotine	ng/mL	4.08	4.09	4.09	0.24	Pass	No	
13	2	45 min	Nicotine	ng/mL	2.52	2.38	2.45	5.71	Pass	No	
14	4	180 min	Nicotine	ng/mL	1.46	1.57	1.52	7.24	Pass	No	
14	3	30 min	Nicotine	ng/mL	3.49	3.45	3.47	1.15	Pass	No	
14	1	20 min	Nicotine	ng/mL	9.75	10.2	9.98	4.51	Pass	No	
14	1	180 min	Nicotine	ng/mL	4.24	4.37	4.31	3.02	Pass	No	
15	5	180 min	Nicotine	ng/mL	3.74	3.62	3.68	3.26	Pass	No	
15	4	45 min	Nicotine	ng/mL	3.56	3.49	3.53	1.98	Pass	No	
15	4	180 min	Nicotine	ng/mL	2.45	2.58	2.52	5.16	Pass	No	
15	3	45 min	Nicotine	ng/mL	3.70	3.33	3.52	10.51	Pass	No	
15	2	45 min	Nicotine	ng/mL	8.18	7.54	7.86	8.14	Pass	No	
15	2	180 min	Nicotine	ng/mL	4.18	4.37	4.28	4.44	Pass	No	
15	1	180 min	Nicotine	ng/mL	4.77	4.74	4.76	0.63	Pass	No	
16	4	30 min	Nicotine	ng/mL	3.86	3.76	3.81	2.62	Pass	No	
16	4	180 min	Nicotine	ng/mL	1.86	2.14	2.00	14.00	Pass	No	

Subject	Visit	Time Point	Analyte	Units	Original Value	Reassay Value	Mean Value	% Difference	Reproducible?	Event?	% of Passing ISR Samples
16	3	180 min	Nicotine	ng/mL	1.82	1.78	1.80	2.22	Pass	No	
16	2	20 min	Nicotine	ng/mL	4.16	4.24	4.20	1.90	Pass	No	
16	1	5 min	Nicotine	ng/mL	22.6	23.3	23.0	3.04	Pass	No	
17	4	30 min	Nicotine	ng/mL	3.35	3.62	3.49	7.74	Pass	No	
17	4	180 min	Nicotine	ng/mL	1.35	1.40	1.38	3.62	Pass	No	
17	3	180 min	Nicotine	ng/mL	1.19	1.31	1.25	9.60	Pass	No	
17	1	180 min	Nicotine	ng/mL	2.56	2.69	2.63	4.94	Pass	No	
11	3	180 min	Nicotine	ng/mL	1.01	DCU	N/AP	N/AP	Fail	N/AP	

Subject	Visit	Time Point	Analyte	Units	Original Value	Reassay Value	Mean Value	% Difference	Reproducible?	Event?	% of Passing ISR Samples
01	5	30 min	Cotinine	ng/mL	120	110	115	8.70	Pass	No	98.6
01	5	180 min	Cotinine	ng/mL	120	118	119	1.68	Pass	No	
01	4	180 min	Cotinine	ng/mL	99.5	100	99.8	0.50	Pass	No	
01	3	180 min	Cotinine	ng/mL	92.8	91.8	92.3	1.08	Pass	No	
01	2	20 min	Cotinine	ng/mL	81.7	75.7	78.7	7.62	Pass	No	
01	1	7.5 min	Cotinine	ng/mL	98.7	95.9	97.3	2.88	Pass	No	
02	5	20 min	Cotinine	ng/mL	108	111	110	2.73	Pass	No	
02	5	180 min	Cotinine	ng/mL	109	117	113	7.08	Pass	No	
02	4	180 min	Cotinine	ng/mL	125	135	130	7.69	Pass	No	
02	3	180 min	Cotinine	ng/mL	123	125	124	1.61	Pass	No	
02	2	180 min	Cotinine	ng/mL	88.3	89.9	89.1	1.80	Pass	No	
02	1	180 min	Cotinine	ng/mL	102	101	102	0.98	Pass	No	
03	4	7.5 min	Cotinine	ng/mL	236	242	239	2.51	Pass	No	
03	4	180 min	Cotinine	ng/mL	236	242	239	2.51	Pass	No	
03	3	180 min	Cotinine	ng/mL	229	234	232	2.16	Pass	No	
03	1	15 min	Cotinine	ng/mL	283	288	286	1.75	Pass	No	
03	1	180 min	Cotinine	ng/mL	260	266	263	2.28	Pass	No	
04	5	10 min	Cotinine	ng/mL	83.2	78.7	81.0	5.56	Pass	No	
04	5	180 min	Cotinine	ng/mL	78.2	59.4	68.8	27.33	Fail	No	
04	4	20 min	Cotinine	ng/mL	115	107	111	7.21	Pass	No	
04	4	180 min	Cotinine	ng/mL	105	98.1	102	6.76	Pass	No	
04	2	30 min	Cotinine	ng/mL	167	162	165	3.03	Pass	No	
04	2	180 min	Cotinine	ng/mL	163	157	160	3.75	Pass	No	

Subject	Visit	Time Point	Analyte	Units	Original Value	Reassay Value	Mean Value	% Difference	Reproducible?	Event?	% of Passing ISR Samples
04	1	5 min	Cotinine	ng/mL	123	134	129	8.53	Pass	No	
05	5	45 min	Cotinine	ng/mL	173	174	174	0.57	Pass	No	
05	5	180 min	Cotinine	ng/mL	161	160	161	0.62	Pass	No	
05	3	30 min	Cotinine	ng/mL	185	188	187	1.60	Pass	No	
05	3	180 min	Cotinine	ng/mL	153	160	157	4.46	Pass	No	
05	2	10 min	Cotinine	ng/mL	259	216	238	18.07	Pass	No	
05	2	180 min	Cotinine	ng/mL	187	197	192	5.21	Pass	No	
06	5	45 min	Cotinine	ng/mL	110	111	111	0.90	Pass	No	
06	5	150 min	Cotinine	ng/mL	101	100	101	0.99	Pass	No	
06	2	180 min	Cotinine	ng/mL	116	121	119	4.20	Pass	No	
07	1	10 min	Cotinine	ng/mL	95.8	94.7	95.3	1.15	Pass	No	
07	1	180 min	Cotinine	ng/mL	85.0	87.2	86.1	2.56	Pass	No	
10	5	30 min	Cotinine	ng/mL	316	331	324	4.63	Pass	No	
10	5	180 min	Cotinine	ng/mL	278	286	282	2.84	Pass	No	
10	4	45 min	Cotinine	ng/mL	256	261	259	1.93	Pass	No	
11	3	20 min	Cotinine	ng/mL	183	183	183	0.00	Pass	No	
11	3	180 min	Cotinine	ng/mL	174	173	174	0.57	Pass	No	
11	2	90 min	Cotinine	ng/mL	175	159	167	9.58	Pass	No	
11	1	180 min	Cotinine	ng/mL	232	234	233	0.86	Pass	No	
12	5	45 min	Cotinine	ng/mL	726	757	742	4.18	Pass	No	
12	5	180 min	Cotinine	ng/mL	682	698	690	2.32	Pass	No	
12	4	180 min	Cotinine	ng/mL	566	576	571	1.75	Pass	No	
12	3	180 min	Cotinine	ng/mL	422	443	433	4.85	Pass	No	

Subject	Visit	Time Point	Analyte	Units	Original Value	Reassay Value	Mean Value	% Difference	Reproducible?	Event?	% of Passing ISR Samples
12	2	20 min	Cotinine	ng/mL	423	439	431	3.71	Pass	No	
12	2	180 min	Cotinine	ng/mL	414	425	420	2.62	Pass	No	
12	1	5 min	Cotinine	ng/mL	534	558	546	4.40	Pass	No	
13	5	45 min	Cotinine	ng/mL	167	163	165	2.42	Pass	No	
13	4	15 min	Cotinine	ng/mL	113	107	110	5.45	Pass	No	
13	4	180 min	Cotinine	ng/mL	96.0	98.6	97.3	2.67	Pass	No	
13	3	30 min	Cotinine	ng/mL	112	107	110	4.55	Pass	No	
13	2	45 min	Cotinine	ng/mL	194	195	195	0.51	Pass	No	
14	4	180 min	Cotinine	ng/mL	185	186	186	0.54	Pass	No	
14	3	30 min	Cotinine	ng/mL	261	288	275	9.82	Pass	No	
14	1	20 min	Cotinine	ng/mL	274	271	273	1.10	Pass	No	
14	1	180 min	Cotinine	ng/mL	251	264	258	5.04	Pass	No	
15	5	180 min	Cotinine	ng/mL	199	198	199	0.50	Pass	No	
15	4	45 min	Cotinine	ng/mL	176	195	186	10.22	Pass	No	
15	4	180 min	Cotinine	ng/mL	165	186	176	11.93	Pass	No	
15	3	45 min	Cotinine	ng/mL	195	189	192	3.13	Pass	No	
15	2	45 min	Cotinine	ng/mL	266	257	262	3.44	Pass	No	
15	2	180 min	Cotinine	ng/mL	241	227	234	5.98	Pass	No	
15	1	180 min	Cotinine	ng/mL	213	197	205	7.80	Pass	No	
16	4	30 min	Cotinine	ng/mL	198	193	196	2.55	Pass	No	
16	4	180 min	Cotinine	ng/mL	162	162	162	0.00	Pass	No	
16	3	180 min	Cotinine	ng/mL	147	138	143	6.29	Pass	No	
16	2	20 min	Cotinine	ng/mL	183	172	178	6.18	Pass	No	

Subject											% of Passing ISR Samples
	Visit	Time Point	Analyte	Units	Original Value	Reassay Value	Mean Value	% Difference	Reproducible?	Event?	
16	1	5 min	Cotinine	ng/mL	178	174	176	2.27	Pass	No	
17	4	30 min	Cotinine	ng/mL	258	256	257	0.78	Pass	No	
17	4	180 min	Cotinine	ng/mL	217	227	222	4.50	Pass	No	
17	3	180 min	Cotinine	ng/mL	216	204	210	5.71	Pass	No	
17	1	180 min	Cotinine	ng/mL	205	198	202	3.47	Pass	No	

Table 8. Incurred Sample Reproducibility Batch Statistics

Nicotine

Batch Number	STD B 0.500 ng/mL	STD C 1.00 ng/mL	STD D 2.00 ng/mL	STD E 4.00 ng/mL	STD F 8.00 ng/mL	STD G 10.0 ng/mL	STD H 20.0 ng/mL	STD I 40.0 ng/mL	STD J 50.0 ng/mL
38	0.498	1.01	1.92	4.23	7.84	10.1	20.9	39.1	48.0
%Theoretical	99.6	101.0	96.0	105.8	98.0	101.0	104.5	97.8	96.0
n	1	1	1	1	1	1	1	1	1

Batch Number	QC A 1.50 ng/mL	QC B 8.00 ng/mL	QC C 37.5 ng/mL	QC C DF2 37.5 ng/mL	QC C DF4 37.5 ng/mL
38	1.45	7.19	38.9	37.4	39.7
	1.43	7.05	36.1	39.5	39.4
				38.1	35.2
Mean	1.44	7.12	37.5	38.3	38.1
S.D.	N/AP	N/AP	N/AP	1.07	2.52
%CV	N/AP	N/AP	N/AP	2.8	6.6
%Theoretical	96.0	89.0	100.0	102.1	101.6
n	2	2	2	3	3

Calibration Curve Parameters:

Regression Method = LINEAR - Weighting Factor = 1/X**2

Slope = 0.245482578

Intercept = 0.00552754113

R-Squared = 0.9983

LLOQ = 0.500 ULOQ = 50.0

Batch Number	STD B 0.500 ng/mL	STD C 1.00 ng/mL	STD D 2.00 ng/mL	STD E 4.00 ng/mL	STD F 8.00 ng/mL	STD G 10.0 ng/mL	STD H 20.0 ng/mL	STD I 40.0 ng/mL	STD J 50.0 ng/mL
39	0.506	0.987	1.92	4.12	7.73	10.2	20.1	40.5	50.1
%Theoretical n	101.2 1	98.7 1	96.0 1	103.0 1	96.6 1	102.0 1	100.5 1	101.3 1	100.2 1

Batch Number	QC A 1.50 ng/mL	QC B 8.00 ng/mL	QC C 37.5 ng/mL	QC C DF2 37.5 ng/mL	QC C DF5 37.5 ng/mL
39	1.47 1.40	7.15 ~ 6.72	36.2 34.1	38.1 35.7 38.0	37.6 35.7 36.6
Mean	1.44	6.94	35.2	37.3	36.6
S.D.	N/AP	N/AP	N/AP	1.36	0.950
%CV	N/AP	N/AP	N/AP	3.6	2.6
%Theoretical n	96.0 2	86.8 2	93.9 2	99.5 3	97.6 3

Flagged Value
~ >15% Theoretical

Calibration Curve Parameters:
Regression Method = LINEAR - Weighting Factor = 1/X**2
Slope = 0.254702648
Intercept = 0.00501091336
R-Squared = 0.9992
LLOQ = 0.500 ULOQ = 50.0

Cotinine

Batch Number	STD B 1.00 ng/mL	STD C 2.00 ng/mL	STD D 4.00 ng/mL	STD E 8.00 ng/mL	STD F 16.0 ng/mL	STD G 40.0 ng/mL	STD H 80.0 ng/mL	STD I 160 ng/mL	STD J 200 ng/mL
38	1.03	1.90	4.02	8.03	15.2	39.8	80.6	162	210
%Theoretical n	103.0 1	95.0 1	100.5 1	100.4 1	95.0 1	99.5 1	100.8 1	101.3 1	105.0 1

Batch Number	QC A 3.00 ng/mL	QC B 37.5 ng/mL	QC C 150 ng/mL	QC C DF2 150 ng/mL	QC C DF4 150 ng/mL
38	2.88 2.75	35.5 33.8	146 142	149 148 144	145 142 135
Mean	2.82	34.7	144	147	141
S.D.	N/AP	N/AP	N/AP	2.65	5.13
%CV	N/AP	N/AP	N/AP	1.8	3.6
%Theoretical n	94.0 2	92.5 2	96.0 2	98.0 3	94.0 3

Calibration Curve Parameters:

Regression Method = LINEAR - Weighting Factor = 1/X**2

Slope = 0.00722264304

Intercept = 0.000630754643

R-Squared = 0.9987

LLOQ = 1.00 ULOQ = 200

Batch Number	STD B 1.00 ng/mL	STD C 2.00 ng/mL	STD D 4.00 ng/mL	STD E 8.00 ng/mL	STD F 16.0 ng/mL	STD G 40.0 ng/mL	STD H 80.0 ng/mL	STD I 160 ng/mL	STD J 200 ng/mL
39	0.971	2.05	4.34	7.68	15.9	38.7	81.5	160	196
%Theoretical n	97.1 1	102.5 1	108.5 1	96.0 1	99.4 1	96.8 1	101.9 1	100.0 1	98.0 1

Batch Number	QC A 3.00 ng/mL	QC B 37.5 ng/mL	QC C 150 ng/mL	QC C DF2 150 ng/mL	QC C DF5 150 ng/mL
39	2.97 2.93	34.1 34.4	140 132	140 137 139	137 144 140
Mean	2.95	34.3	136	139	140
S.D.	N/AP	N/AP	N/AP	1.53	3.51
%CV	N/AP	N/AP	N/AP	1.1	2.5
%Theoretical n	98.3 2	91.5 2	90.7 2	92.7 3	93.3 3

Calibration Curve Parameters:

Regression Method = LINEAR - Weighting Factor = 1/X**2

Slope = 0.00759048648

Intercept = -0.000212390581

R-Squared = 0.9980

LLOQ = 1.00 ULOQ = 200

FIGURES

Figure 1. Calibration Curve – Nicotine

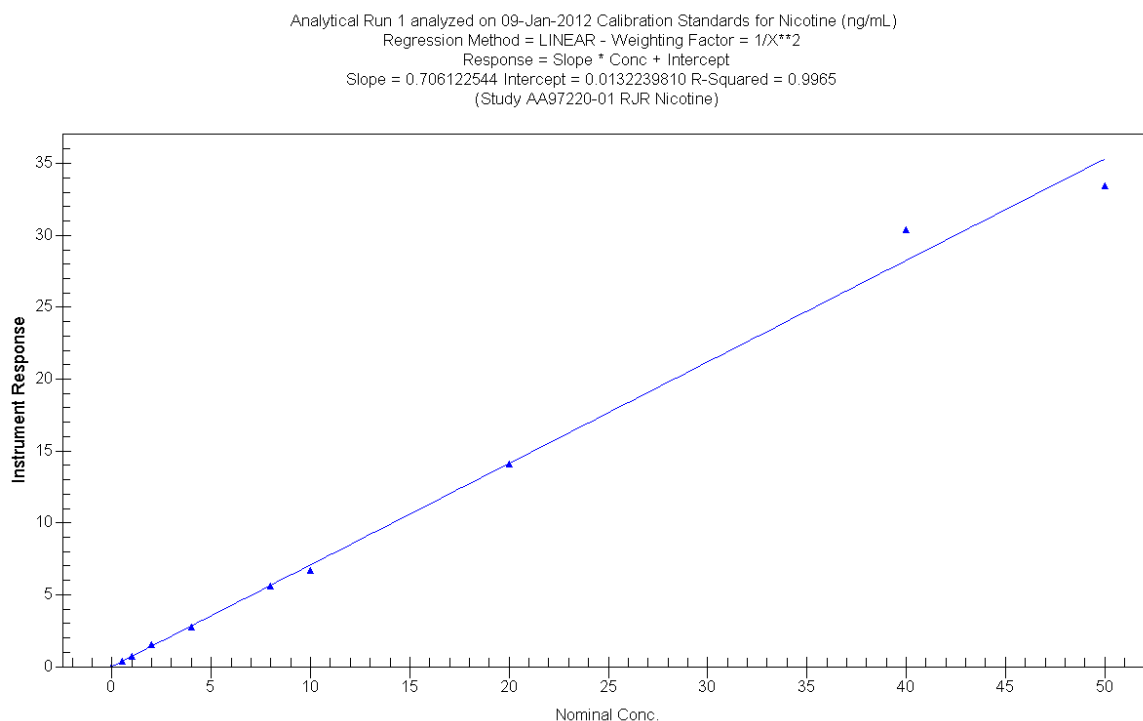
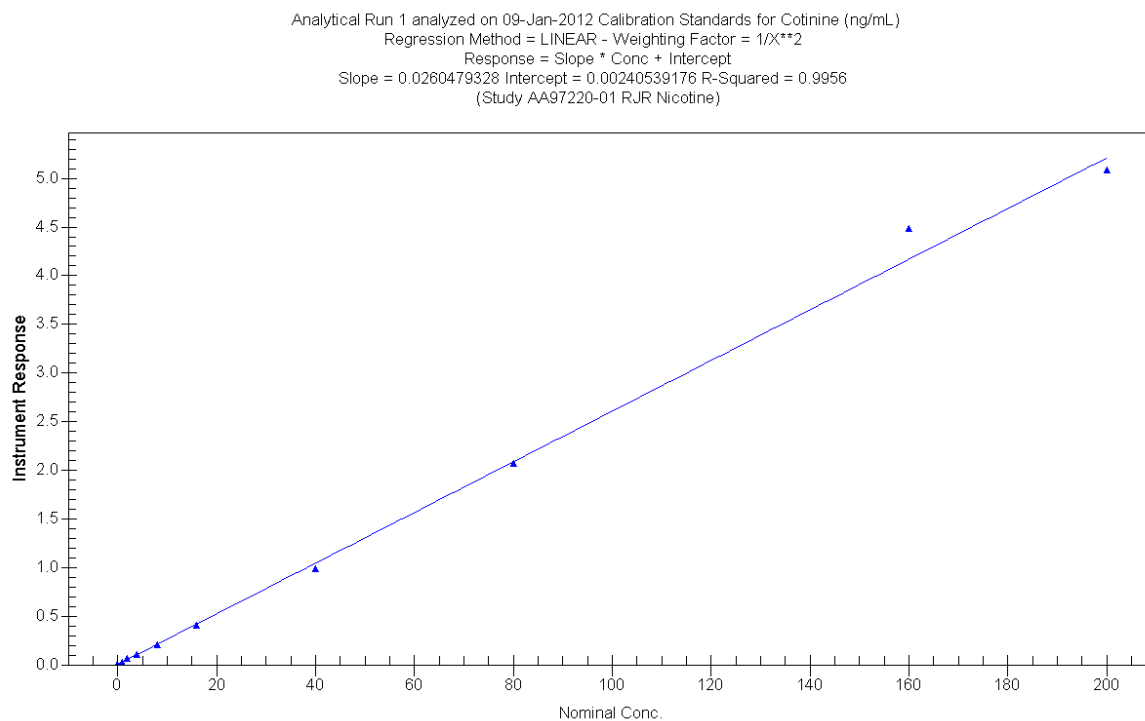


Figure 2. Calibration Curve – Cotinine



ATTACHMENTS

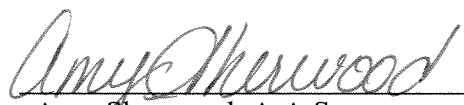
Attachment 1. Quality Assurance Statement

QUALITY ASSURANCE

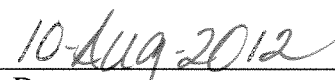
Various portions of this study were audited by the Quality Assurance Unit of Celerion and were checked for compliance with applicable Federal Regulations and Celerion Standard Operating Procedures.

The dates the audits were performed, the areas audited, and the dates the audit reports were submitted to Celerion management are listed below.

Area Audited	Date of Audit	Date Audit Issued to Celerion Management
Sample Analysis Plan	22-Nov-2011	22-Nov-2011
In Process	05, 10-Jan-2012	10-Jan-2012
Database	13, 16-Feb-2012	16-Feb-2012
Bioanalytical Report	07, 08-Aug-2012	08-Aug-2012



Amy Sherwood, A.A.S.
Quality Assurance Auditor



Date

Attachment 2. Sample Analysis Plan



621 Rose Street
Lincoln, NE 68502 USA
www.celerion.com
Tel: 402-476-2811
Toll Free: 800-776-1716
Fax: 402-939-0428

SAMPLE ANALYSIS PLAN

Bioanalysis of Nicotine and Cotinine in Human Serum In Support of Clinical Protocol CSD1101:

Assessment of Smokers' Nicotine Uptake and Urge to Smoke after Use of Smokeless Tobacco Products

R.J. Reynolds Tobacco Company
Product Integrity, Research and Development
Bowman Gray Technical Center
950 Reynolds Blvd.
Winston-Salem, North Carolina 27102

Celerion-Lincoln Study: AA97220-01

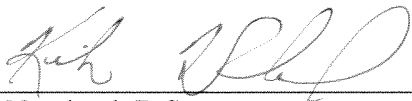
Kirk Newland, B.S.
Bioanalytical Principal Investigator
Celerion
621 Rose Street
Lincoln, NE 68502

Date: 28-Nov-2011

COMPLIANCE STATEMENT

This study will be performed according to applicable GLP requirements and in compliance with Standard Operating Procedures (SOPs) in effect in the bioanalytical laboratory of Celerion, Lincoln, Nebraska. The SOPs are written based on the principles and requirements described in 21 CFR Part 58.

The Bioanalytical Principal Investigator has overall responsibility for the technical conduct of the study, as well as for the interpretation, analysis, documentation, and reporting of results, and represents the single point of control for the study.



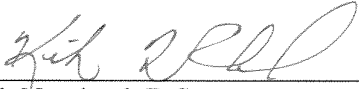
Kirk Newland, B.S.
Bioanalytical Principal Investigator

28-Nov-2011

Date

SIGNATURES

SAP Prepared by:



Kirk Newland, B.S.
Bioanalytical Principal Investigator

28-Nov-2011
Date

SAP Approved by:



Aaron May, B.S.
Associate Director of Production, Bioanalytical Services

28-NOV-2011
Date

SAP Reviewed by:



Amy Sherwood, A.A.S.
Quality Assurance Auditor

28 NOV-2011
Date

Approved by:



Eckhardt Schmidt, Ph.D.
Sponsor Contact
R.J. Reynolds Tobacco Company

November 28, 2011
Date

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ACRONYMS AND ABBREVIATIONS

Acronyms/Abbreviations	Meaning
°C	degree Celsius (centigrade)
µg	microgram
AB	Applied Biosystems
API	atmospheric pressure ionization
BAM	bioanalytical method
BLK	blank
CDER	Center for Drug Evaluation and Research
CFR	Code of Federal Regulations
CV	coefficient of variation
Da	Dalton
EDTA	ethylenediaminetetraacetic acid
EXT	extraction
g	gram
GLP	good laboratory practices
h	hour
HDPE	high density polyethylene
HPLC	high performance liquid chromatography
ID	identification
INC	incongruous
INS	instrumentation
IS	internal standard
ISA	insufficient volume for full analysis
ISP	incomplete sample processing
ISR	incurred sample reproducibility
ISV	insufficient volume
IVR	insufficient volume to reassay
L	litre, liter
LLOQ	lower limit of quantitation
LNK	Celerion, Lincoln site
M	molar
mg	milligram
mL	millilitre, milliliter
mol	mole
MS	mass spectrometry
MW	molecular weight
n	number of data
N/AP	not applicable
N/AV	not available
NFV	not full volume
ng	nanogram
No.	number
NU	not used

Acronyms/Abbreviations	Meaning
OECD	Organization for Economic Cooperation and Development
PE	Perkin Elmer
Pd	Period
pg	picogram
QC	quality control
QCs	quality control samples
REF	reference
RI	reinjection
Rm.T.	room temperature
RR	reanalysis
RVL	remaining volume low
S.D.	standard deviation
SOP	standard operating procedure
SPE	solid-phase extraction
SST	system suitability test
STD	standard
Sub	subject
SVD	sample volume depleted
TBD	to be determined
Temp	temperature
ULOQ	upper limit of quantitation
USP	US pharmacopeia
\bar{x}	mean

1. PURPOSE OF THE BIOANALYTICAL STUDY

The purpose of the bioanalytical study is to determine the concentration of nicotine and cotinine in human serum study samples using a validated LC-MS/MS bioanalytical method.

2. MATERIAL - REFERENCE ITEM(S)

Only appropriately characterized and currently certified reference standards will be used for quantitation purposes.

3. METHOD SUMMARY

(b) (4)



4. COMPUTER APPLICATION PROGRAMS

Instrument specific software

Applied Biosystems Analyst[®] version 1.5.1

Watson[™] Bioanalytical LIMS version 7.3 for Windows

Labnotes[™] Web Client 1.10.4

Higher versions may be used; this will be documented in the bioanalytical report.

5. STUDY SAMPLES

5.1. Sample Source and Date of Receipt

The clinical study protocol number CSD1101 specified that up to 20 subjects would be recruited for randomization to have approximately 16 subjects complete the study. Sixteen timepoints are to be collected from each subject per test or period.

Number of study samples planned to be analyzed	Approximately 1600
Sample Shipment to Celerion ^a	Approximately week of 03-Jan-2012
Sample Arrival	Approximately by: 06-Jan-2012
Sample Storage Temperature	Approximately -80°C
Analysis	Single analysis of all samples
Sample Pre-dilutions	No sample dilutions anticipated

^a The actual date(s) will be recorded in the study documentation and in the bioanalytical report.

5.2. Study Timelines

<i>Sample Analysis Start</i>	<i>January 2012</i>
Preliminary Data Available	January 2012
Sponsor Selected Repeats Provided by	February 2012
Complete Preliminary Data Available	February 2012
QA Reviewed Data Available	March 2012
Electronic Data Transfer of QA'd Data to CCD's DM group	March 2012
Draft Bioanalytical Report Provided for Review	March/April 2012
Final QA'd report to RJRT (pdf and hardcopy)	March/April 2012

5.3. Sample Management

After arrival, study samples will be logged into the LIMS (Laboratory Information Management System) of Celerion. The Sponsor and/or clinical representative will be informed of any discrepancy between individual sample identification and the shipment documentation.

Upon arrival of samples at Celerion's Shipping and Receiving department, the shipping/receiving personnel will retrieve the shipment and complete the appropriate documentation included with the shipment by initialing/signing and dating application forms. The signed/dated shipment document(s) will be returned to the Sponsor and study (shipping) site with notes indicating sample status at receipt. Faxing or e-mailing the scanned document(s) will be acceptable. A copy of the faxed or e-mailed shipping document will be placed in the appropriate study file(s).

6. DESCRIPTION OF AN ANALYTICAL RUN

Study samples will be analyzed according to the requirements of the clinical study design. When possible, all study samples for a given subject will initially be analyzed within the same analytical batch.

An analytical run, at a minimum, will contain ≥ 2 blank samples (to reflect at least 2% of the study samples), 2 standard zero samples (blank sample with the internal standard added), and a minimum of 1 replicate of 8 different calibration standards (non-zero standard samples).

A number of ≥ 2 QC samples at a minimum of 3 concentrations will be included to reflect at least 5% of the number of study samples. As required, dilution integrity of study samples is verified by the inclusion of at least 3 dilution QC samples (high QC samples may be used as dilution QC samples, if applicable), diluted in the same way as the study samples (for each dilution factor).

7. ANALYTICAL RUN ACCEPTANCE CRITERIA

(b) (4)



8. REASSAYS

8.1. Reassay For Analytical Reasons

If study samples are identified to be reassayed, these will be conducted according to Celerion SOPs.

8.2. Analytical Investigation

On occasion, unexpected analytical results may be obtained for individual study samples. Such values are defined as Events and are investigated and documented (refer also to [Section 9.2](#)). An Event Investigation may not always find an assignable cause that addresses the unexpected result. Hypotheses are formed with various possibilities of explaining the unexpected result. If a cause is not determined, the sample may be coded 'Value Requiring Confirmation' (VRC) and reassayed for confirmatory purposes.

If sufficient sample volume remains, VRC reassays are prepared and analyzed at least in singlet and preferably in duplicate or triplicate. The results are reported according to Celerion SOPs.

Bracketing samples (BSS) may be reassayed along with VRC samples. The bracketing samples selected and the reason for including bracketing study samples is documented before reassay. If required, back-up samples will be used for analysis.

8.3. Incurred Sample Reproducibility

The purpose of Incurred Sample Reproducibility (ISR) testing is to demonstrate that the analysis of clinical samples is reproducible for a given bioanalytical method, study population, and bioanalysis site.

Clinical samples will be selected for repeat analysis from multiple analytical runs. The selected samples should represent the concentration range observed in the study.

Based on the approximate (1600) samples anticipated in protocol CSD1101. If the number of study samples exceeds 1000, 5% will be selected for ISR analysis. If the number of samples is smaller than 1000, 10% will be selected for ISR analysis.

ISR testing through repeat analysis of the clinical samples will be performed within the validated stability period for the bioanalytical method when possible.

The paired analysis will be considered acceptable if the repeat analysis has a percent difference $\leq 20\%$. The ISR testing will be considered acceptable if $> 66.7\%$ of the reassayed values meet pair matching criteria.

8.4. Sponsor Selected Reassays

The Sponsor may request the reassay of study samples. The Sponsor must authorize the reassays in writing. It is the responsibility of the Sponsor to establish the reassay procedure prior to the initiation of study sample reanalysis. This procedure must be documented and it must specify the reason samples are selected for reassay and how they are reported prior to the reassay of samples. These samples are to be identified as ‘SSR’ (Sponsor Selected Reassay).

9. STUDY ADMINISTRATION

9.1. Quality Assurance

The Quality Assurance Unit (QAU) will review the Sample Analysis Plan (and any amendment(s)), and inspect the raw data and the final bioanalytical report (and any amendment(s)). All findings will be reported to the the Bioanalytical Principal Investigator and Management. A Quality Assurance statement will be issued at the end of the bioanalytical study. The QAU, as dictated by the contract with the Sponsor, will audit as least 1 critical phase during the execution of the study. Critical phases will include sample receipt, the preparation of stocks, standard calibration samples and quality controls, clinical sample aliquoting and extraction, as well as the instrument analysis of the extracted samples.

9.2. Event Investigations and Deviations

Unexpected occurrences and/or results will be investigated as an “Event” and documented according to Celerion SOPs. The impact of the Event on the study will be assessed and documented in the “[Analytical Notes](#)” section of the final bioanalytical report.

Deviations to an SOP, Clinical Protocol, or Sample Analysis Plan will be documented according to Celerion SOPs. This will describe the deviation and the action that was taken to resolve the issue. An assessment will be made of the impact on the study by the Bioanalytical Principal Investigator. All non-editorial deviations will be summarized in the “Analytical Notes” section of the Bioanalytical Report.

The QAU will review and sign all documentation for each Event Investigation or Deviation.

9.3. Reporting of Bioanalytical Study Results

According to the contract, there are 3 deliverables: 1) preliminary excel file transfer to RJRT to check data; 2) final electronic data transfer to CDD (according to specifications agreed-upon by Celerion and CDD); 3) final QA’d report (with QA statement as to what has been audited when and to who results were reported and when) in pdf and electronically.

Bioanalytical study sample results will be provided to the Sponsor and CDD in Microsoft Excel™ .xlsx file format (using 3 significant figures). Data will be reported with ng/mL as the units of measure.

When determining the concentration of study samples, no extrapolation is permitted beyond the nominal values of the LLOQ and the ULOQ standards used to define the validated range. If necessary, samples are reassayed according to Celerion SOPs.

Celerion will provide a draft bioanalytical report for Sponsor's review. If no comments are received within 90 days, Celerion reserves the right to issue the final bioanalytical report. The electronic copy in Adobe® Acrobat PDF format of the signed final bioanalytical report will be forwarded to the Sponsor and Comprehensive Drug Development (CDD). The original hardcopy of the bioanalytical report will be archived at Celerion.

The final bioanalytical report will be sent to R.J. Reynolds Tobacco Company and CDD on CD. All corrections to the signed final bioanalytical report will be performed by means of an amendment. In addition, data will be electronically transferred to CDD's database according to agreed-upon specifications between CDD and Celerion. Celerion and CDD are responsible for the ensuring that the transfer preserved data accuracy.

10. DATA STORAGE AND ARCHIVING

All relevant project-related documentation, electronic data, and study correspondence will be stored at the Celerion, Lincoln, Nebraska site archive for a period of no less than 10 years as described in Celerion Local Operations SOPs.

11. REFERENCES

Guidance for Industry – Bioanalytical Method Validation: US Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER), Center for Veterinary Medicine (CVM) May 2001

Protocol Title: "Assessment of Smokers' Nicotine Uptake and Urge to Smoke after Use of Smokeless Tobacco Products"

Bioanalytical Method SOP for the Determination of Nicotine and Cotinine in Human Serum, Celerion Study AA33664-05

12. CELERION GLOBAL AND LOCAL STANDARD OPERATING PROCEDURE TABLE OF CONTENTS

Global SOP and Quality Manual Division CGSOP.xxxx and CGQM.0001 Series

Title	Document Number	Version Number	Effective Date
Celerion Global Quality Manual	CGQM.0001	3	20-Oct-2011
Process and Standards Document Control ¹	CGSOP.0001	2	31-Aug-2011
Good Documentation Practices	CGSOP.0002	2	24-May-2011
Handling Research Misconduct	CGSOP.0003	2	20-Apr-2011
Master Validation Plan	CGSOP.0004	1	17-Feb-2011
Quality Issue Investigations and Corrective/Preventive Action	CGSOP.0005	1	01-Apr-2011
IT Security Policy	CGSOP.0006	2	28-Oct-2011
ANVISA Regulatory Compliance	CGSOP.0007	1	05-Aug-2011
SharePoint Management	CGSOP.0008	1	13-Oct-2011
Compliance to 21 CFR Part 11	GBL-SOP-02	1	30-Sep-2010
Purchasing Control	GBL-SOP-04	1	30-Sep-2010
Data Retention ²	GBL-SOP-05	1	30-Sep-2010

Global Bioanalytical Services Division GSOP.01.xxxx, GL-BIO-xxxxx, or GBL-BAS G-xxx Series

Title	Document Number	Issue Number	Effective Date
Archiving Electronic Data in Bioanalytical	GSOP.01.0001	1	17-Feb-2011
Labnotes™ Definition Control and Revision	GSOP.01.0002	1	17-Feb-2011
Documentation of a Deviation	GSOP.01.0004	1	11-Apr-2011
Documentation of Stock, Substock, Standard, and QC Solutions in Labnotes™	GSOP.01.0006	1	06-Apr-2011
Labnotes™ System Management	GSOP.01.0007	2	07-Oct-2011
Method Validation of Immunogenicity Assays	GSOP.01.0012	1	20-Oct-2011
Principal Investigator and Sample Analysis Plan	GL-BIO-10600	03	27-Jul-2010
Chromatographic and Spectrometric Methods: Calibration Curve Preparation, Specifications and Acceptance Criteria	GL-BIO-10602	06	27-Jul-2010

¹ Note to File Attached

² Deviation Attached

Global Bioanalytical Services Division GSOP.01.xxxx, GL-BIO-xxxxx, or GBL-BAS G-xxx Series			
Title	Document Number	Issue Number	Effective Date
Reporting of Data and the Reassay of Samples	GL-BIO-10603	04	20-Jun-2010
Reference Standard Receipt, Preparation, Storage, and Disposal	GL-BIO-10604	03	27-Jul-2010
Qualification of Analytical Instruments and Equipment	GL-BIO-10605	03	10-Jun-2010
Quantitative Ligand-Binding Assays: Validation	GL-BIO-10606	04	09-Apr-2010
Quantitative Ligand-Binding Assays: Calibration Curve Preparation, Assay Specifications and Acceptance Criteria	GL-BIO-10607	05	10-Jun-2010
Event Resolution	GL-BIO-10608	04	30-Sep-2010
Chromatographic Peak Identification, Review and Acceptance	GL-BIO-10610	02	27-May-2010
Refrigerators, Freezers and Controlled Temperature Area	GL-BIO-10613	01	20-Aug-2010
Reports and Report Amendments	GL-BIO-10615	02	10-Aug-2010
Study Correspondence	GL-BIO-10616	01	06-Aug-2010
Master Schedule for Non-Clinical Laboratory Studies	GL-BIO-10619	02	10-Aug-2010
Chromatographic Method Development – Experimental Design and R & D Summary Documentation	GL-BIO-10620	02	27-Jul-2010
Method Qualification of a Chromatographic Assay	GL-BIO-10622	03	24-Jun-2010
Method Validation of a Chromatographic Assay	GL-BIO-10623	03	23-Aug-2010
Content of Study Plans and Protocols for Method Validation	GL-BIO-10624	02	27-Jul-2010
Incurred Sample Reproducibility	GL-BIO-10630	04	30-Sep-2010
Biological Matrix Receipt, Storage, and Disposal	GL-BIO-10632	02	03-Jun-2010
Labnotes™ Device Installation	GL-BIO-10633	03	10-Jun-2010
LBS and CBA Method Development Design, Qualification, and Documentation	GL-BIO-10635	03	10-Jun-2010
Equipment Qualification and Maintenance Using Labnotes™	GL-BIO-10636	02	24-Jun-2010
Balance Qualification and Maintenance in Labnotes™	GL-BIO-10637	03	19-Apr-2010
Pipette Qualification and Maintenance in Labnotes™	GL-BIO-10638	03	19-May-2010
Chemicals and Materials Receipt, Storage, and Disposal Using Labnotes™	GL-BIO-10642	02	09-Apr-2010
Reagent Solution Documentation in Labnotes™	GL-BIO-10643	01	04-Jun-2010
Hosting a Regulatory Inspection in BAS	GBL-BAS G-004	02	24-Jun-2010
Hosting a Client Audit in BAS	GBL-BAS G-005	02	24-Jun-2010
Customer Quality Complaint Management in BAS	GBL-BAS G-006	02	24-Jun-2010
Training and Records in Bioanalysis	GBL-BAS G-007	02	07-Sep-2010

Global QA BIO SOPs – GSOP.09.xxxx and GL-ESD QA-xxxx Series			
Title	Document No.	Issue No.	Effective Date
Quality Assurance Audit Reports	GL-ESD QA-12001	02	30-Sep-2010
Internal Audit Program	GL-ESD QA-12003	02	30-Sep-2010
System/Process Audit	GL-ESD QA-12004	03	30-Sep-2010
Responding to Regulatory and Client Findings in ESD	GL-ESD QA-12008	02	30-Sep-2010
Vendor Audits	GL-ESD QA-12009	02	30-Sep-2010
Validation Deliverable Auditing Process	GL-ESD QA-12010	02	30-Sep-2010
Audit of Study Related Submissions in BAS	GL-ESD QA-12012	02	30-Sep-2010
Critical Phase Inspections	GL-ESD QA-12016	01	30-Sep-2010
Vendor Audit Program Management	GSOP.09.0002	01	12-Jan-2011

Global EHS SOPs – GSOP.05.xxxx Series			
Title	Document No.	Issue No.	Effective Date
Radiation Safety	GSOP.05.0001	1	08-Feb-2011
Bloodborne Pathogen Exposure Control Plan ²	GSOP.05.0002.L	1	05-May-2011
Chemical Hygiene Plan for Laboratory Operations ²	GSOP.05.0003.L	1	31-May-2011
Facility and Environmental Compliance Plan ²	GSOP.05.0004.L	1	31-May-2011
Emergency Action and Fire Prevention Plan ²	GSOP.05.0005.L	1	31-May-2011
Hazard Communication Plan ²	GSOP.05.0006.L	1	21-Jun-2011
Injury and Illness Prevention Plan ²	GSOP.05.0007.L	1	12-Jul-2011
Determination and Shipping of Biohazardous Materials	GSOP.05.0009	1	31-Aug-2011
Waste Analysis Plan	GSOP.05.0010	1	23-Aug-2011
Use and Storage of Peroxide-Forming Chemicals	GSOP.05.0012	1	31-Aug-2011

² Deviation Attached

Bioanalytical Services Division – 03.01.xxx and LNK SOP.00xx Series			
SOP Title	Document No.	Issue No.	Effective Date
Lincoln BAS (Bioanalytical Services) Management Responsibilities	LNKSOP.0001	1	29-Oct-2010
Equipment with Temperature Control Calibration	LNKSOP.0005	1	24-Oct-2011
Operation and Maintenance of Plate Washers	LNKSOP.0009	1	06-Jun-2011
Sample Management Pre-analysis	LNKSOP.0012	1	28-Jul-2011
Sample Management During Analysis	LNKSOP.0013	1	28-Jul-2011
Sample Management Post-analysis	LNKSOP.0014	1	28-Jul-2011
Freezer and Refrigerator Monitoring and Maintenance	LNKSOP.0015	1	28-Jul-2011
SoftMax[®] Pro Enterprise Edition	LNKSOP.0016	1	21-Sep-2011
SoftMax[®] Pro Enterprise Edition Data Transfer	LNKSOP.0017	1	21-Sep-2011
Operation and Maintenance of Plate Readers	LNKSOP.0018	1	21-Sep-2011
Laboratory Documentation	LNKSOP.0022	1	30-May-2011
Operation and Maintenance of Oxidizers	LNKSOP.0026	2	28-Nov-2011
Document Control in Bioanalytical	LNKSOP.0030	1	13-Sep-2011
Absorption, Distribution, Metabolism, and Excretion (ADME) Studies	LNKSOP.0031	1	21-Oct-2011
General Safety and Emergency Instructions	03.01.004	18	05-Aug-2010
Power Failure Instructions	03.01.011	16	05-Aug-2010
Bioanalysis Principal Investigator Responsibilities	03.01.036	10	30-Sep-2010
Training Documentation of Bioanalytical Associates³	03.01.044	9	28-Jul-2010
Working Instructions	03.01.048	5	28-Sep-2010
Reinjections	03.01.049	5	30-Sep-2010
Recertification of Internal Standards by LCMS for Identity and Isotopic Purity Confirmation	03.01.052	3	06-Sep-2010
Archiving and Retrieving of Studies and Data in LabnotesTM	03.01.056	2	20-Sep-2010
Bioanalytical Method (BAM) Procedures, BAM SOPs, and System Settings	03.01.057	3	29-Apr-2010

³ Documentation of Deviation Attached

Bioanalytical Services Division – 03.01.xxx and LNK SOP.00xx Series			
SOP Title	Document No.	Issue No.	Effective Date
Non-electronic Raw Data in a Binder	03.01.059	5	10-Jun-2010
Creating an UISR Report Using Inspector Software	03.01.060	3	20-Sep-2010
Event Management and Resolution	03.01.062	3	30-Sep-2010
Archiving and De-archiving of Studies in Watson™	03.01.064	3	20-Sep-2010
Archiving Electronic Data	03.01.065	3	29-Sep-2010
In-House Whole Blood and Urine Collection	03.01.066	2	10-Jun-2010
Glassware Washing and Suitability⁴	03.01.067	2	10-Jun-2010
Bioanalytical Master Signature List	03.01.068	2	10-Jun-2010
SOP Processes and Document Control in Bioanalytical	03.01.069	3	24-Jun-2010
Change Control	03.01.071	5	30-Sep-2010
Method Qualification of a Chromatographic Assay	03.01.077	5	30-Sep-2010
Method Validation of a Chromatographic Assay	03.01.078	8	17-Sep-2010
Chromatographic Validation Protocols	03.01.079	3	30-Sep-2010
System Suitability Criteria	03.01.091	2	30-Sep-2010
Quality Control Review of Analytical Data	03.01.096	3	30-Sep-2010
Solution Expiry Assignment and Labeling in the Bioanalytical Laboratory	03.01.108	2	07-Sep-2010
Reference Compound Weighing and Witnessing	03.01.110	2	30-Sep-2010
Reporting of Data and Reassay of Samples	03.01.111	2	30-Sep-2010
Stock Comparisons	03.01.113	2	30-Sep-2010
Validation for Quantitative Biomarker Assays	03.01.117	1	26-Jul-2010

Bioanalytical Services Division – 03.02.xxx Series			
SOP Title	Document No.	Issue No.	Effective Date
Laboratory Equipment Operation and Maintenance Procedures	03.02.047	14	30-Sep-2010
Radioisotope Detectors	03.02.049	8	30-Sep-2010
Plate Readers	03.02.051	8	30-Sep-2010

⁴ Documentation of Deviation Attached

Bioanalytical Services Division – 03.02.xxx Series			
SOP Title	Document No.	Issue No.	Effective Date
Barnstead NANOpure® Water Systems	03.02.057	7	10-Jun-2010
ELAN DRCe ICP-MS	03.02.061	3	30-Sep-2010
Operation and Use of the Savant Evaporator	03.02.062	3	18-Aug-2010
Shimadzu HPLC System	03.02.069	3	29-Jun-2010
Calibration and Maintenance of the Sciex Quadrupole Mass Spectrometers	03.02.071	1	12-Jul-2010
Maintenance of ELAN DRCe ICP-MS	03.02.072	2	30-Sep-2010
Instrument Analysis of an LCMS or HPLC Batch	03.02.073	3	30-Sep-2010
Daily Operation of the Zymark (Caliper) Sciclone ALH 3000	03.02.074	2	05-Aug-2010
Maintenance and Calibration of the Zymark (Caliper) Sciclone ALH 3000 Robot	03.02.075	2	30-Sep-2010
Operation, Maintenance, and Calibration of the Centrifuges	03.02.076	2	30-Sep-2010
Operation and Maintenance of Cohesive HTLC System	03.02.077	2	10-Jun-2010
Operation and Maintenance of Jasco Pumps	03.02.078	2	10-Jun-2010
Maintenance of Perkin Elmer Pumps	03.02.079	2	10-Jun-2010
Fluorescence Detectors	03.02.080	2	10-Jun-2010
Operation and Maintenance of Autosamplers	03.02.081	1	31-May-2010
Operation and Maintenance of Tecan Genesis® RSP	03.02.084	1	10-Jun-2010

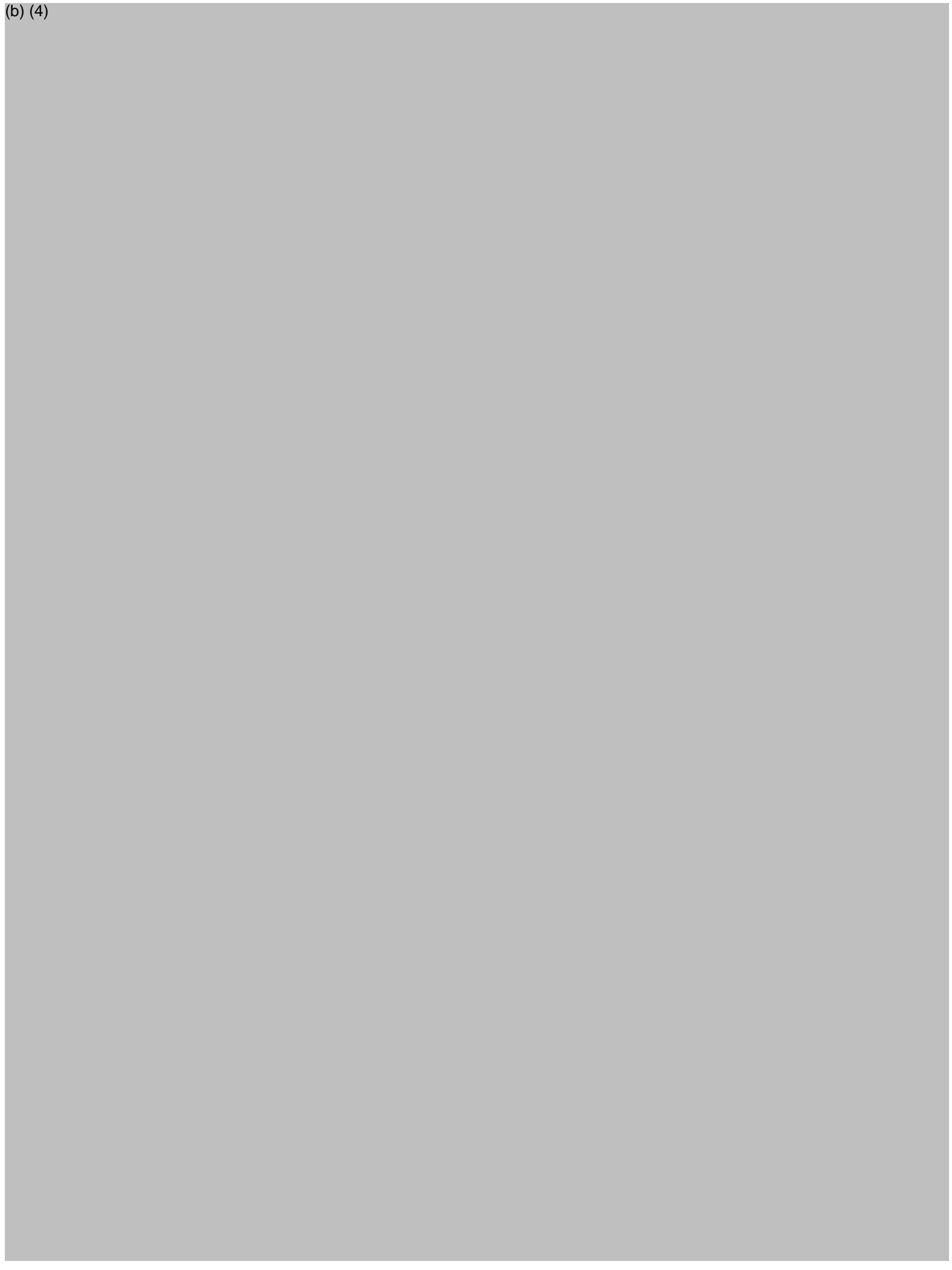
Site Management Division – 15.01.xxx Series			
Archiving Methods and Procedures	15.01.003	6	23-Jul-2010

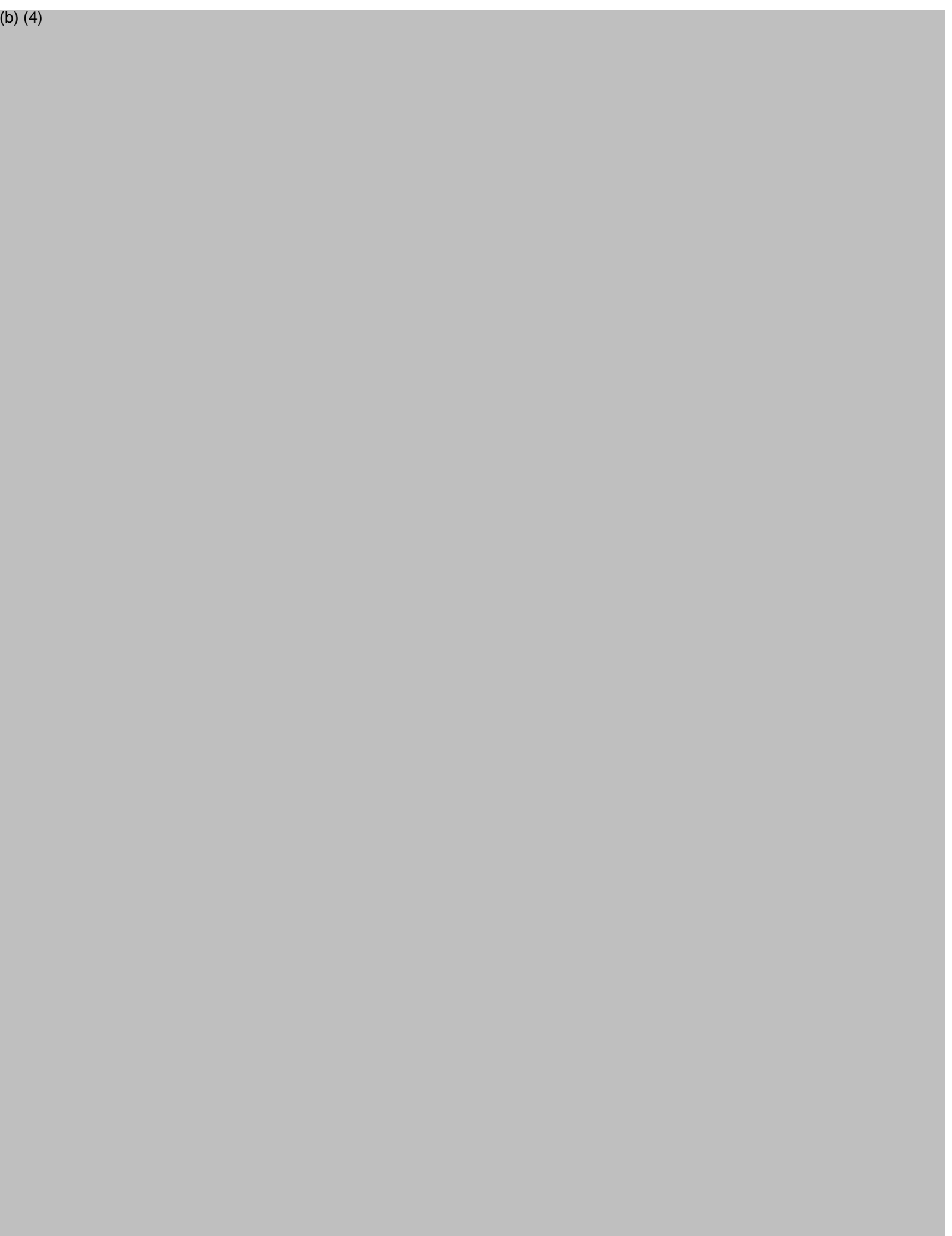
Lincoln Site Division – LNKSOP.02xx Series			
SOP Title	Document No.	Issue No.	Effective Date
Lincoln Disaster Recovery Plan	LNKSOP.0205	1	30-Aug-2011
Lincoln Security Plan	LNKSOP.0300	1	30-Sep-2011

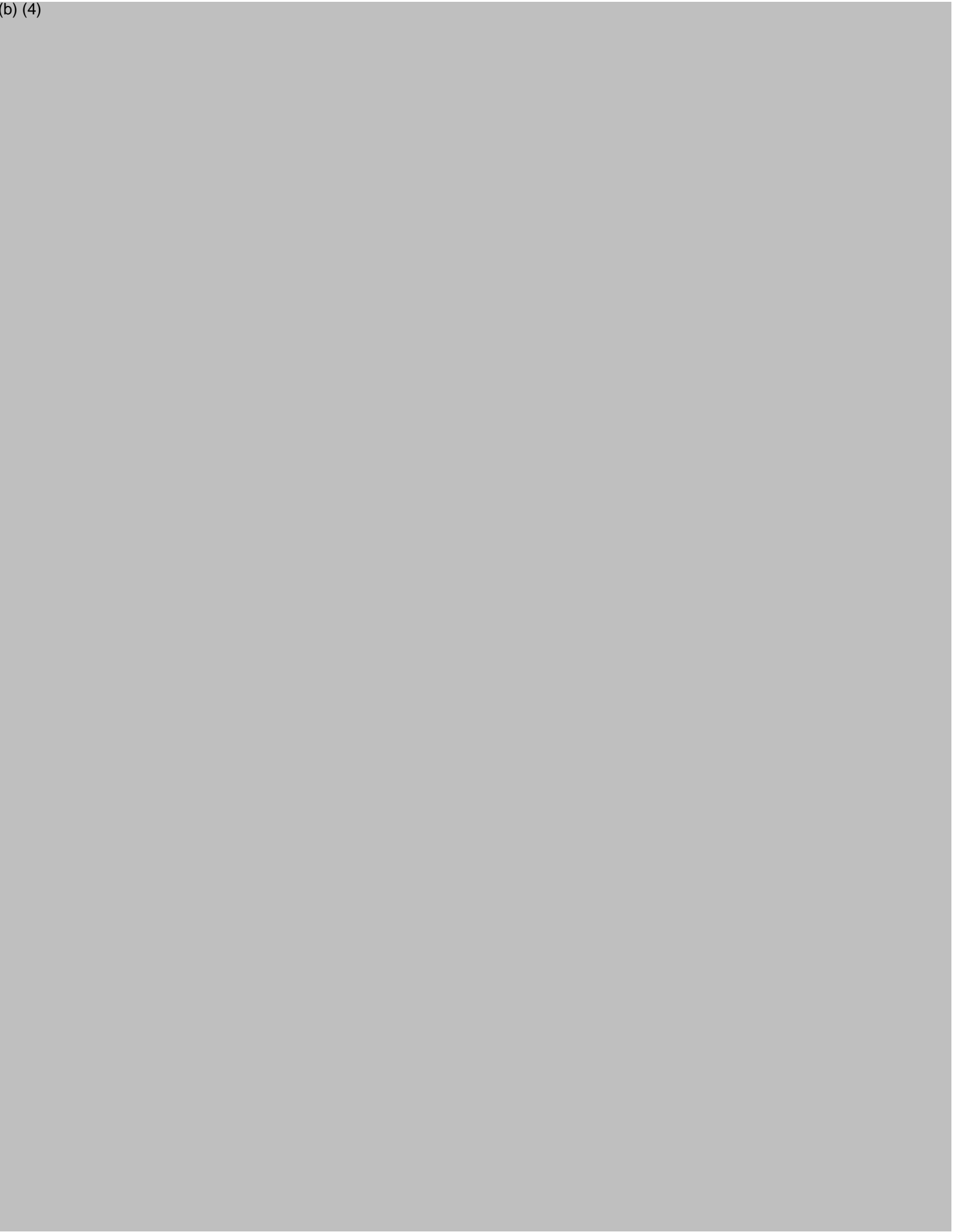
Attachment 3. Method Validation Report







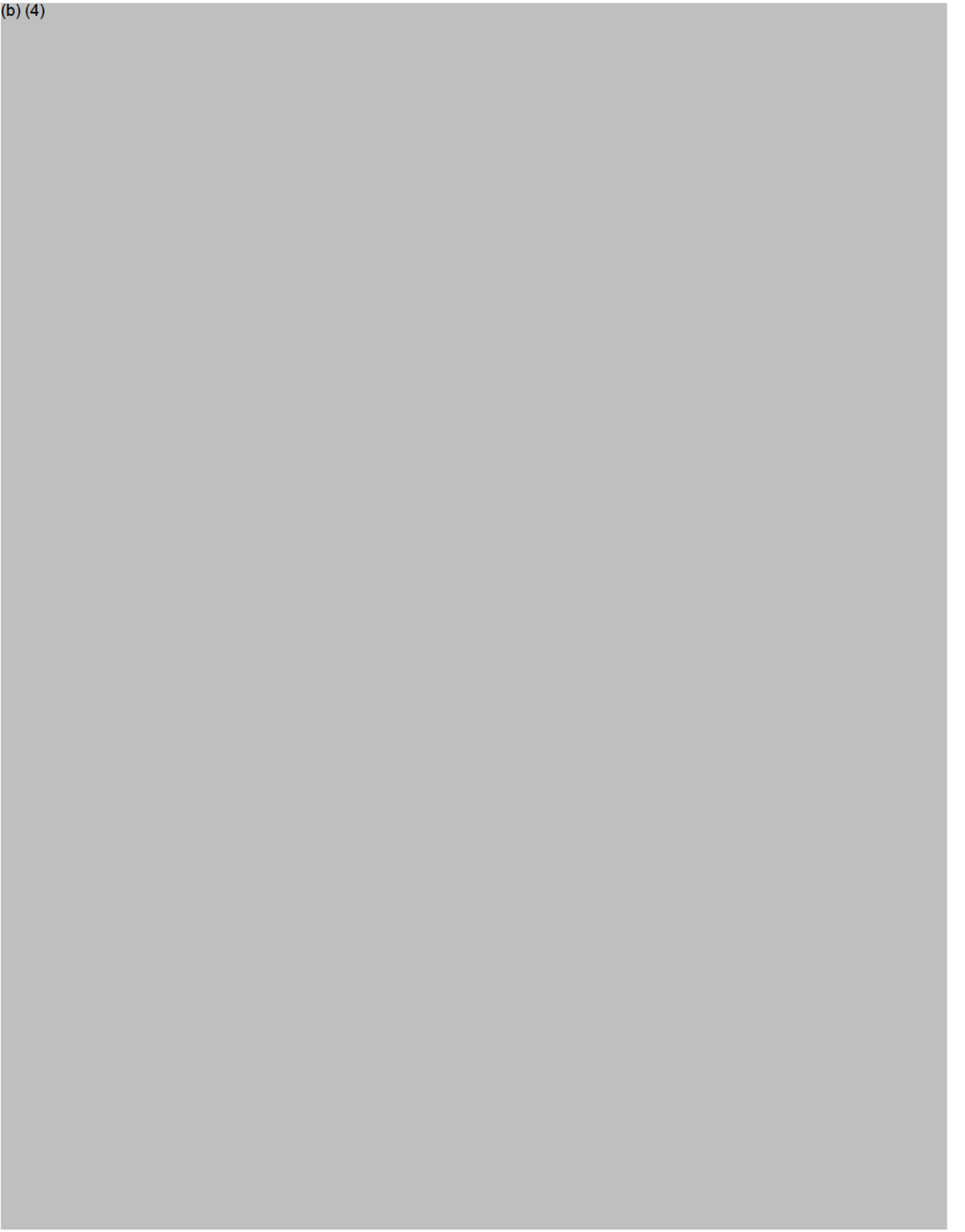


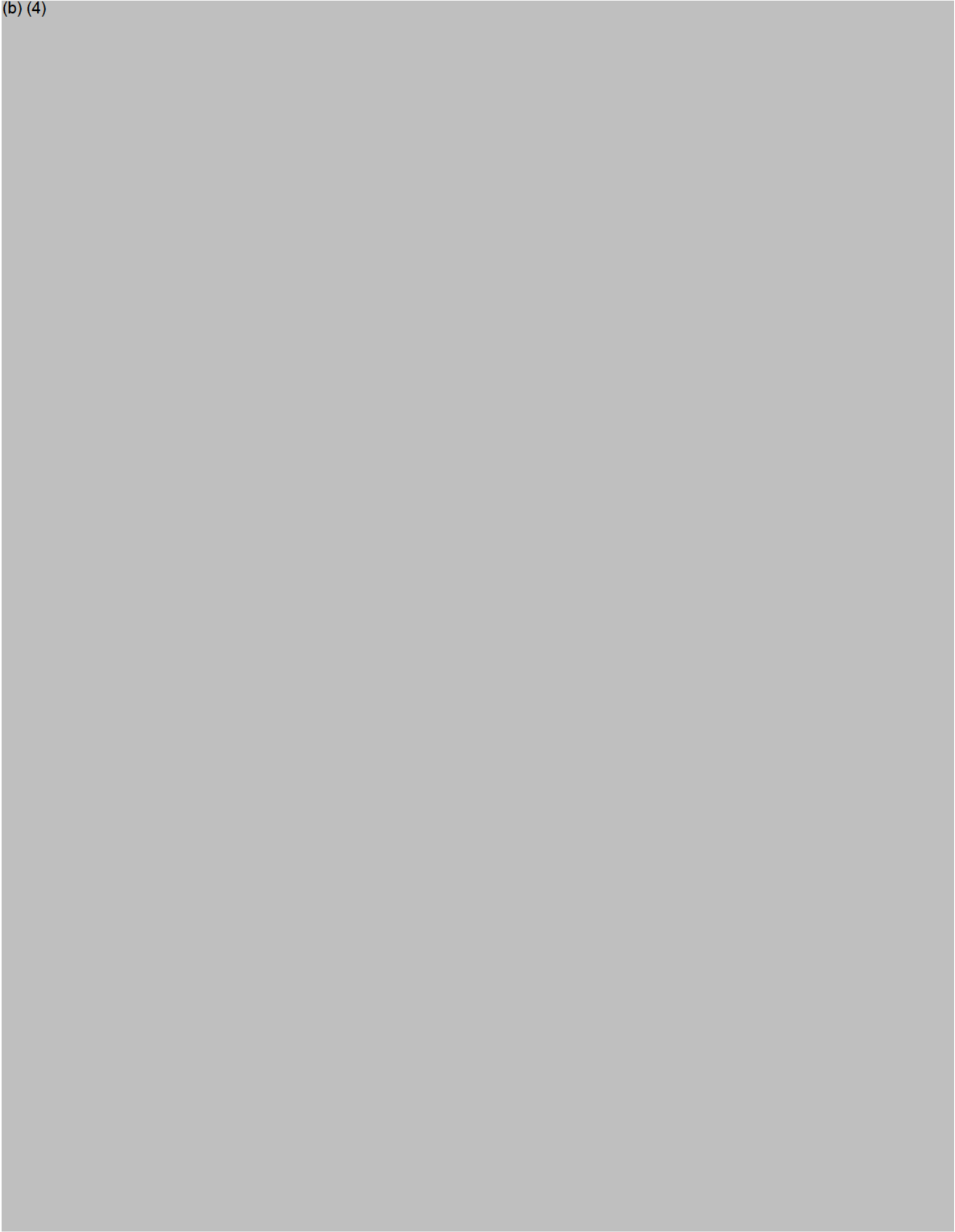


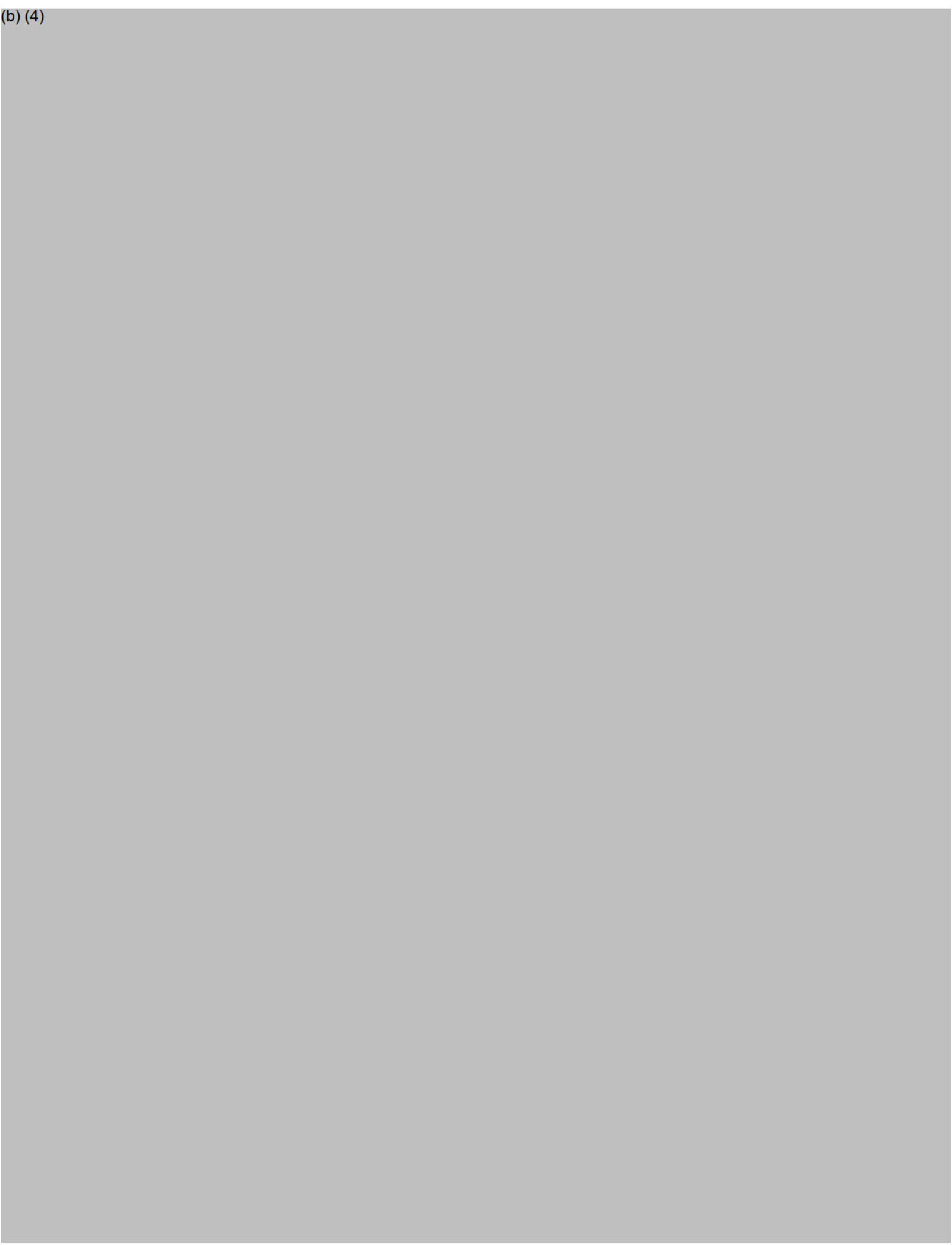










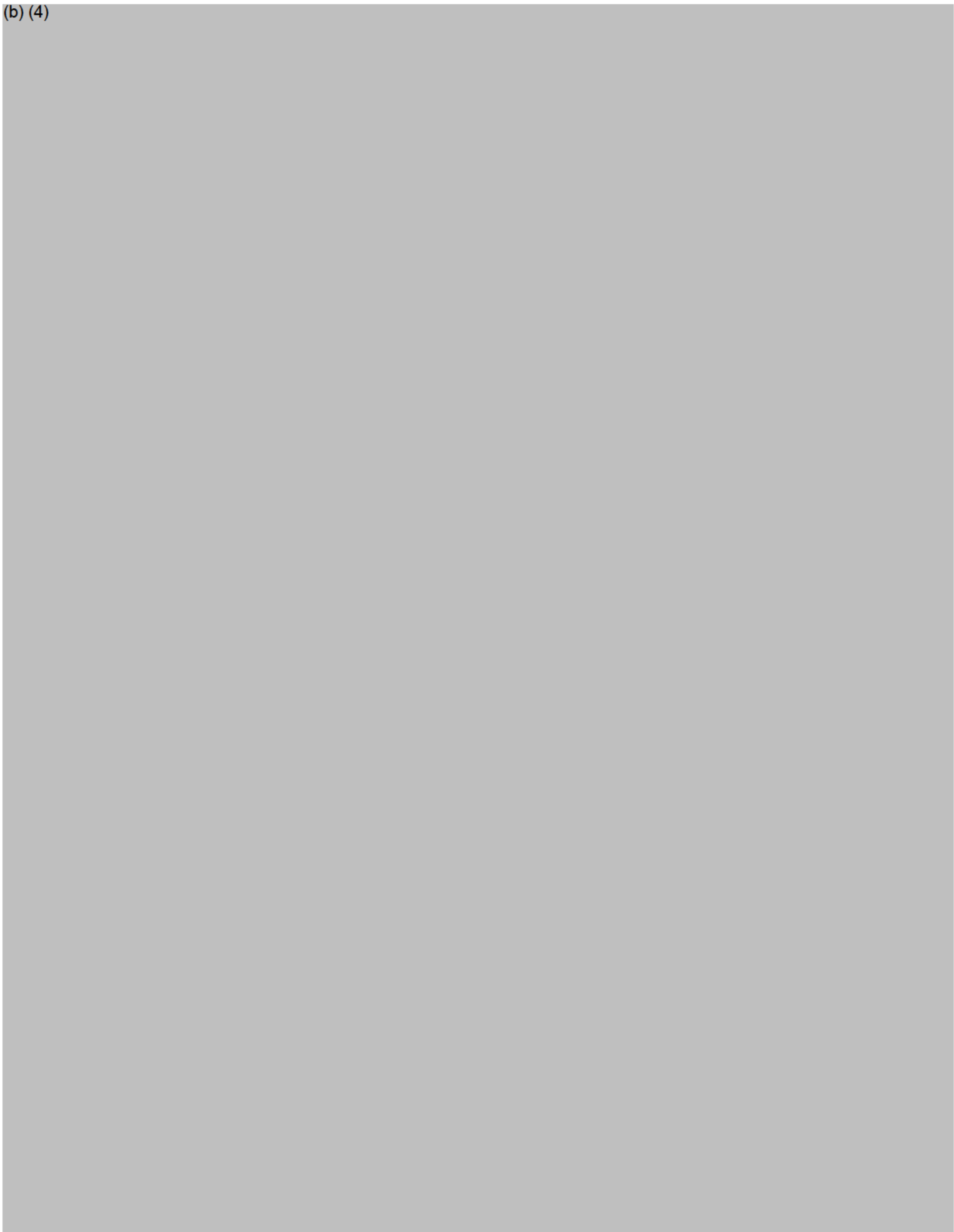












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ATTACHMENTS

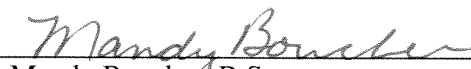
Attachment 1. Quality Assurance Statement


QUALITY ASSURANCE

Various portions of this study were audited by the Quality Assurance Unit of Celerion and were checked for compliance with applicable Federal Regulations and Celerion Standard Operating Procedures.

The dates the audits were performed, areas audited, and the dates the audit reports were submitted to Celerion management are listed below.

Area Audited	Date of Audit	Date Audit Issued to Celerion Management
Database	20, 22-Mar-2010	22-Mar-2010
BAM SOP	20, 22-Mar-2010	22-Mar-2010
Validation Report	05, 06-Apr-2010	06-Apr-2010
Amendment 1	30-Sep-2010	30-Sep-2010
Amendment 2	28, 29-Mar-2011	29-Mar-2011
Amendment 3	21-Oct-2011	21-Oct-2011


Mandy Boucher, B.S.
Quality Assurance Auditor


Date

Attachment 2. Validation Protocol



621 Rose Street
Lincoln, NE 68502 USA
www.celerion.com
Tel: 402-476-2811
Toll Free: 800-776-1716
Fax: 402-939-0428

AMENDMENT 1 TO VALIDATION PROTOCOL

**VALIDATION OF AN LC-MS/MS METHOD FOR THE DETERMINATION OF
NICOTINE AND COTININE IN HUMAN SERUM**

Study: AA33664-05

Celerion
621 Rose Street
Lincoln, NE 68502

Date: 12-Apr-2010


Distribution: Original (1): Celerion (Archives)
 Duplicate (1): Project Leader
 Quality Assurance Associate – Bioanalytical
 Bioanalytical Principal Investigator

Confidential – Property of Celerion
Contents may not be used, divulged, published, or otherwise disclosed without the consent of Celerion.

AMENDMENT SIGNATURE PAGE


<u>Amendment No.</u>	<u>Description</u>	<u>Date</u>
1	Globally changed MDS Pharma Services to Celerion Changed management in Section 3	April 2010

The April 2010 amendments have been reviewed and approved by the individuals listed below.



Mandy Boucher
Quality Assurance Auditor – Bioanalytical
Celerion, Lincoln, Nebraska

12 Apr 2010
Date

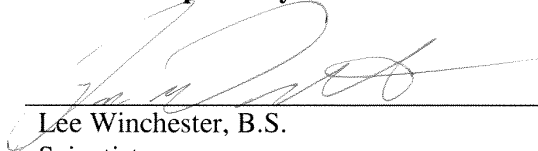


Kirk Newland, B.S.
Bioanalytical Principal Investigator
Celerion, Lincoln, Nebraska

12-Apr-2010
Date

SIGNATURES

Protocol Prepared by:



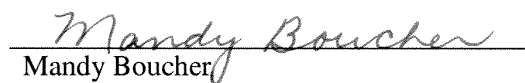
Lee Winchester, B.S.

Scientist

MDS Pharma Services, Lincoln, Nebraska

18-FEB-2010
Date

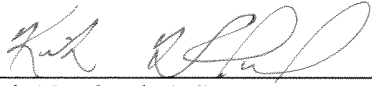
Protocol Reviewed by:



Mandy Boucher
Quality Assurance Auditor – Bioanalytical
MDS Pharma Services, Lincoln, Nebraska

19 Feb 2010
Date

Approved by:



Kirk Newland, B.S.
Bioanalytical Principal Investigator
MDS Pharma Services, Lincoln, Nebraska

19-Feb-2010

Date

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COMPLIANCE STATEMENT

This study will be performed in compliance with Standard Operating Procedures (SOP) in place in the Bioanalytical Laboratory of Celerion, Lincoln, Nebraska. The SOPs are written based on the principles and requirements described in 21 CFR Part 58.

This validation study will be conducted in accordance with the guidelines documented in this protocol, which was written to follow the procedures documented in the current local SOP 03.01.078 in effect entitled "Method Validation of a Chromatographic Assay" and the current SOP GL-BIO-10602 in effect entitled "Chromatographic and Spectrometric Methods: Calibration Curve Preparation, Specifications and Acceptance Criteria." Critical deviations from the SOPs and validation protocol will be covered in the final validation report and documented with the raw data according to the current local SOP 03.01.061 in effect entitled "Documentation of a Deviation." The stability of instrument response throughout a batch will be evaluated according to the current local SOP 03.01.091 in effect entitled "System Suitability Criteria". Chromatographic peak integration will be reviewed prior to regression of the standard curve according to the current SOP GL-BIO-10610 in effect entitled "Chromatographic Peak Identification, Review and Acceptance."

The Bioanalytical Principal Investigator has overall responsibility for the technical conduct of the study, as well as for the interpretation, analysis, documentation, and reporting of results, and represents the single point of control for the study.



Kirk Newland, B.S.
Bioanalytical Principal Investigator
MDS Pharma Services, Lincoln, Nebraska

19-Feb-2010

Date

1. OBJECTIVE

This protocol describes the experimental procedures and acceptance criteria for the method validation of an LC-MS/MS method for the determination of nicotine and cotinine in human serum.

2. SPONSOR

Name:	Celerion
Address:	621 Rose Street Lincoln, Nebraska 68502
Study Monitor (SM):	Not Applicable

3. TEST FACILITY

Name:	Celerion	
Address:	621 Rose Street Lincoln, Nebraska 68502	
Bioanalytical Principal Investigator (BPI):	Kirk Newland, B.S. Bioanalytical Principal Investigator Celerion, Lincoln, Nebraska	BPI Phone: 402-437-4719 BPI FAX: 402-939-0428 BPI e-mail: Kirk.Newland@celerion.com
Management:	Staci McDonald, Pharm.D. Director, Bioanalytical Services Celerion, Lincoln, Nebraska	Phone: 402-437-4712 FAX: 402-939-0428 e-mail: Staci.McDonald@celerion.com

4. PROPOSED STUDY SCHEDULE

Study Initiation: Defined by the signature of the Bioanalytical Principal Investigator on the validation protocol

Experimental Start of Study: February 2010

Experimental End of Study: February 2010

Study Completion: Defined by the signature of the Bioanalytical Principal Investigator on the final validation report

5. EXPERIMENTAL

5.1. Reference Items

All calculations will be based on the purity/potency provided. Any details not available here will be recorded in the study documentation and in the final validation report.

	Analyte	Internal Standard (IS)
ID	Nicotine	d ₃ -Nicotine
Source	*	*
Lot No.	*	*
Purity/Potency	*	*
Expiry Date	*	*
Storage Conditions*	Ambient temperature	-20°C

	Analyte	Internal Standard (IS)
ID	Cotinine	d ₃ -Cotinine
Source	*	*
Lot No.	*	*
Purity/Potency	*	*
Expiry Date	*	*
Storage Conditions*	Ambient temperature	5°C

* = Actual source, lot number, purity/potency, expiry date, and storage conditions will be documented in the study documentation and in the final validation report.

Certificates of analysis will be available on file at Celerion, Lincoln, Nebraska.

5.2. Assay Parameters

Nicotine Calibration Standard Concentrations:	0.500, 1.00, 2.00, 4.00, 8.00, 10.0, 20.0, 40.0, and 50.0 ng/mL
Nicotine Quality Control Concentrations:	1.50, 8.00, 37.5, and 1950 ng/mL
Cotinine Calibration Standard Concentrations:	1.00, 2.00, 4.00, 8.00, 16.0, 40.0, 80.0, 160, and 200 ng/mL
Cotinine Quality Control Concentrations:	3.00, 37.5, 150, and 7800 ng/mL
Quality Control Storage Temperature:	-20°C

5.3. Calibration Standard and Quality Control Sample Preparation

Quality control (QC) samples will be prepared in bulk, aliquoted, and stored frozen at a nominal temperature of -20°C. Calibration standards (STD) will be freshly prepared on the day of extraction.

5.4. Analytical Method

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5.5. Biological Matrix

Human serum, will be collected in-house at Celerion, Lincoln, Nebraska. Human serum will be screened for interference at the retention time and mass transitions of nicotine, cotinine, d₃-nicotine (IS), and d₃-cotinine (IS). Individual human serum lots free of significant interference will be used as control matrix and for the preparation of standards and quality control samples during the validation.

5.6. Test System

The test system will consist of a PerkinElmer® Series 200 Micro Pump or equivalent and LEAP Technologies CTC PAL or equivalent equipped with an AB SCIEX | MDS Sciex API 4000 triple quadrupole mass spectrometer. Computer application programs used to acquire and derive data for this study will include AB SCIEX | MDS Sciex Analyst™ 1.4.1 and Watson™ LIMS 7.3, respectively.

5.7. Response Function

Standard curve linearity and quantitation of nicotine and cotinine will be determined by applying a regression model of weighted linear (1/concentration²).

6. VALIDATION PROCEDURE

6.1. Validation Conduct

The analytical method was developed at Celerion, Lincoln, Nebraska. The method was adapted according to current needs. The validation will be conducted at Celerion for a targeted range of 0.500 – 50.0 ng/mL for nicotine and 1.00 – 200 ng/mL for cotinine in human serum using a target serum volume of 0.300 mL.

The validation of the assay will be performed in accordance with Celerion Standard Operating Procedures, which follow the FDA guidance for the validation of bioanalytical methods. The validation results will be presented in the validation report.

6.2. Description of a Validation Batch (PA and Non-PA Batches)

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Acceptance Criterion:

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6.3. System Suitability

6.3.1. Summary of Minimum Requirements for System Suitability Injections

Each batch will begin with 5 replicates of upper limit of quantitation (ULOQ) extracted system suitability (EXTSYSHI) samples, followed by a minimum of one sample free of analyte and internal standard, and a lower limit of quantitation (LLOQ) extracted system suitability (EXTSYSLO) sample. Each batch will end with 2 replicates of EXTSYSHI samples, followed by a minimum of one sample free of analyte and internal standard, and an EXTSYSLO sample.

6.3.2. Instrument Stability

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Acceptance Criterion:

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6.3.3. Instrument Response

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Acceptance Criterion:

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6.3.4. Carryover Evaluation

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Acceptance Criterion:

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6.4. Validation Batch Acceptance Criteria

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6.5. Presentation of Validation Results

Statistical results for calibration standards and calibration curve parameters from all accepted precision and accuracy (PA) batches will be tabulated and reported, excluding calibration standard data from the processed sample integrity (PSI) evaluation batch.

All QC sample results within accepted PA batches, whether or not they are within the stated QC acceptance ranges, will be included in the statistics. However, QC samples coded for analytical reasons will not be included [for example: Incomplete Sample Processing (ISP), Unacceptable Chromatography (UCR), or Unacceptable Internal Standard Response (UISR)].

7. VALIDATION COMPONENTS

7.1. Precision and Accuracy (Inter-Batch and Intra-Batch)

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Acceptance Criteria for Inter-Batch and Intra-Batch Evaluation:

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7.2. Selectivity and Matrix Effect

7.2.1. Blank Matrix Selectivity

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Acceptance Criteria:

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7.2.2. Matrix Effect

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Acceptance Criteria:

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7.2.3. Multiple Analytes Measured by Assay

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Acceptance Criteria:

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7.2.4. Co-administered Compounds

This test will not be performed as there are no specifically required co-administered compounds. Please note that it is known that some dosing forms (tobacco smoke) contain many similar analytes. At this time, there has been no indication of an issue with nicotine or cotinine selectivity based on the dosing form.

7.2.5. Known Metabolites, Isomers, and Endogenous Compounds

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Acceptance Criteria:

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7.2.6. Hemolyzed Sample Integrity

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Acceptance Criteria:

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7.2.7. Turbid Sample Integrity

This test will not be performed at this time because turbid serum free of nicotine cannot be purchased to accurately evaluate the impact of sample turbidity on the assay. The test could be assessed at a later time when nicotine free turbid serum is available.

7.3. Sensitivity

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Acceptance Criteria:

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7.4. Recovery

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Acceptance Criterion:

(b) (4)



7.5. Stability

7.5.1. Long-Term (Frozen) Stability in Matrix

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Acceptance Criteria:

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7.5.2. Freeze-Thaw and Short-Term Stability in Matrix

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Acceptance Criteria:

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7.5.3. Post-Preparative Stability

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Acceptance Criteria:

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7.5.4. Long-Term Stability for Stock Solutions

Stability for stock solutions can be taken from previous validations of nicotine and cotinine, Celerion Studies AA33664, Groups 1 – 4.

7.5.5. Short-Term Stability for Stock Solutions

Stability for stock solutions can be taken from previous validations of nicotine and cotinine, Celerion Studies AA33664, Groups 1 – 4.

7.5.6. Stability of Analyte During Sample Collection and Handling

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Acceptance Criteria:

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7.5.7. Sample Aliquot Frozen Storage Stability

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7.6. Integrity Evaluations

7.6.1. Dilution Integrity

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Acceptance Criteria:

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7.6.2. Automated Sample Aliquot Integrity

- This test will not be performed since the caution needed to clean supplies does not make robotic sample handling very feasible.

7.6.3. Processed Sample Integrity

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Acceptance Criteria:

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7.7. Stress Test

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Acceptance Criteria:

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8. STUDY ADMINISTRATION

8.1. Data Review

The review will include, but will not be limited to:

- Verification that documentation meets the requirements of Celerion SOPs
- Verification of calculations
- Clarity of documentation
- Evaluation of results
- Acceptance or rejection of batches

8.2. Data Processing

Chromatographic peak integration will be reviewed prior to regression of the standard curve according to the current SOP GL-BIO-10610 in effect. The Bioanalytical Principal Investigator must approve any changes to base lines after the data have been regressed. All validation data will be acquired and integrated with the regression algorithm and weighting documented in [Section 5.7](#) using AB | MDS Sciex Analyst™ 1.4.1 and Watson™ LIMS 7.3, respectively. All concentration data will be reported to 3 significant figures.

8.3. Quality Assurance Review

The Quality Assurance unit will review the validation protocol (and any amendments) and audit the raw data and results after completion of the bench work portion of the validation study (database review). The Quality Assurance unit will review the validation report prior to issuance. All findings will be reported to the Bioanalytical Principal Investigator.

8.4. Validation Protocol Amendments

Any intended change to the validation protocol will be documented in an amendment to the validation protocol. Each amendment will indicate the reason for the change, the impact on the study, and be sequentially numbered, dated, signed by the Bioanalytical Principal Investigator, and distributed to all recipients of the validation protocol.

8.5. Study Deviations

All deviations (unintended changes) from the SOPs and validation protocol will be described and acknowledged by dated signature from the Bioanalytical Principal Investigator in the study documentation, and critical deviations will be included (and discussed where necessary) in the validation report.

8.6. Distribution of Validation Protocol and Amendments

- Project Leader
- Quality Assurance Associate – Bioanalytical
- Bioanalytical Principal Investigator

9. REPORTING OF VALIDATION DATA

Celerion will write a validation report based on the Celerion validation report template. The report will contain, but may not be limited to, the following: study purpose, materials and methods (including critical deviations from the SOPs and validation protocol), validation results, an evaluation of the validation results (accuracy, precision, and curve parameters), and representative chromatograms.

The report will include a Quality Assurance statement listing the inspections undertaken for the study and the extent that the report reflects the raw data.

An electronic copy (Adobe® Acrobat®.pdf) of the final validation report (i.e. the signed report) will be forwarded to the Sponsor. The original bound hardcopy of the validation report will be archived at Celerion.

10. ARCHIVING

All raw data, associated data, and the report will be archived at Celerion, Lincoln, Nebraska, according to the SOP in effect during the conduct of the study.

11. REFERENCES

Guidance for Industry – Bioanalytical Method Validation: US Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER), Center for Veterinary Medicine (CVM) May 2001

Celerion. Validation of an LC-MS/MS Method for the Determination of Nicotine, Cotinine and 3'transhydroxy-Cotinine in Human Plasma (EDTA). Celerion Study AA33664-01. Lincoln, Nebraska. Report Date 12-Jan-2009.

Celerion. Validation of an LC-MS/MS Method for the Determination of Nicotine, Cotinine and 3'transhydroxy-Cotinine in Human Plasma (Heparin). Celerion Study AA33664-02. Lincoln, Nebraska. Report Date 06-Feb-2007.

Celerion. Validation of an LC-MS/MS Method for the Determination of Nicotine, in Human Plasma (EDTA). Celerion Study AA33664-03. Lincoln, Nebraska. Report Date 29-Oct-2007.

Celerion. Validation of an LC-MS/MS Method for the Determination of Nicotine, in Human Plasma (EDTA). Celerion Study AA33664-04. Lincoln, Nebraska. Report Date 02-Jun-2007.

Analytical Determination of Nicotine and Related Compounds and Their Metabolites. Elsevier 1999.

Attachment 4. Certificate(s) of Analysis

Attachment 5. Individual Run Reports

Individual Run Reports for All Accepted Batches

The Watson™ LIMS-generated Individual Run Reports are provided to demonstrate key elements such as peak area of the analyte, peak area of the internal standard, the ratio of analyte to internal standard, and the concentration for each calibration curve standard, quality control sample and subject sample assayed. For each accepted batch, these reports are divided into three separate tables:

- 1) Standard Sample Data
- 2) QC Sample Data
- 3) Study Sample Data

The Standard Sample Data table demonstrates the data obtained for calibration curve standards in each batch. Each calibration curve standard is represented by the corresponding nominal concentration. The corresponding STD identifier, i.e. STD C, can be found in the table for Back-calculated Calibration Curve Standard Concentrations.

The QC Sample Data table demonstrates the data obtained for quality control samples in each batch. Each quality control sample is represented by the corresponding nominal concentration. The corresponding QC identifier, i.e. QC A, can be found in the table for Quality Control Sample Data (Between-batch Precision and Accuracy). Samples appearing in the QC Sample Data table with a nominal concentration of 0.00 are System Suitability samples included for monitoring the stability of the instrument response. Accuracy criteria are not applicable; therefore, no nominal concentrations are assigned. The System Suitability samples are entered in Watson™ LIMS to facilitate the calculation of precision (%CV) and “drift” – the percent difference between calculated concentrations of System Suitability samples in the middle or at the end of the batch from those at the beginning of the batch.

The Study Sample Data table demonstrates the data obtained for subject samples in each batch. Each subject sample is represented by the subject number, time, and unique barcode number. In some cases, the terminology Treatment ID or Treatment Code reflects the period, not the randomization scheme.

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 1
 Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		0	656208 825	0 000000	-0 0923		-0 0573	-86 6
9	0 00		1388 43	759571 628	0 001828	-0 0222			
10	1 00	1 00000	21764 703	802474 858	0 027122	0 949	-5 1		
11	2 00	0 250000	43265 363	715391 797	0 060478	2 23	11 5		
12	4 00	0 0625000	84783 563	795725 171	0 106549	4 00	0 0		
13	8 00	0 0156250	179507 223	877452 982	0 204578	7 76	-3 0		
14	16 0	0 00390625	305140 951	742788 442	0 410805	15 7	-1 9		
15	40 0	0 000625000	697710 341	707432 628	0 986257	37 8	-5 5		
16	80 0	0 000156250	1464279 453	708516 419	2 066684	79 2	-1 0		
17	160	0 0000390625	3084833 114	687605 472	4 486342	172	7 5		
18	200	0 0000250000	3477789 644	683697 658	5 086736	195	-2 5		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:

Slope = 0 0260479328

Intercept = 0 00240539176

R-Squared = 0 9956

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 1
 Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	3617742 817	718955 173	5 031945	1	193		194		4 2
2	0 00	3275219 201	673138 92	4 865592	1	187				
3	0 00	3237693 429	669146 731	4 838540	1	186				
4	0 00	3261181 637	655835 587	4 972560	1	191				
5	0 00	3335111 122	658394 02	5 065525	1	194				
91	0 00	3065614 941	562615 89	5 448860	1	209				
92	0 00	3054702 133	584136 705	5 229430	1	201				
30	3 00	51934 315	618887 088	0 083916	1	3 13	4 3	3 19	6 3	2 4
63	3 00	50682 82	584188 631	0 086758	1	3 24	8 0			
41	37 5	622677 367	618571 131	1 006638	1	38 6	2 9	38 7	3 2	0 4
74	37 5	621537 599	614240 11	1 011881	1	38 8	3 5			
52	150	2609131 981	646184 685	4 037750	1	155	3 3	165	10 0	8 1
89	150	2183105 681	481264 885	4 536183	1	174	16 0			

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)
 AAR - Concentration Found is Greater than 200 (Highest Standard)

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 1
Serum, Concentration of Cotinine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
01	N/A	1 / Day 1 - 0 0333h	1917171 135	622015 707	3 082191	1	118	23	05104620000017	AA97220-01 05104620000017 01 N/A Serum-1 1 / Day 1 - 0333h
01	N/A	1 / Day 1 - 0 0333h	1594125 539	620158 062	2 570515	1	98 6	21	05104620000033	AA97220-01 05104620000033 01 N/A Serum-1 1 / Day 1 - 0333h
01	N/A	1 / Day 1 - 0 0333h	1338184 333	646136 121	2 071056	1	79 4	20	05104620000049	AA97220-01 05104620000049 01 N/A Serum-1 1 / Day 1 - 0333h
01	N/A	1 / Day 1 - 0 0333h	1654602 742	670956 135	2 466037	1	94 6	22	05104620000065	AA97220-01 05104620000065 01 N/A Serum-1 1 / Day 1 - 0333h
01	N/A	2 / Day 1 0h	1690493 481	591057 739	2 860116	1	110	26	05104620000018	AA97220-01 05104620000018 01 N/A Serum-1 2 / Day 1 0h
01	N/A	2 / Day 1 0h	1498692 984	578374 366	2 591216	1	99 4	25	05104620000034	AA97220-01 05104620000034 01 N/A Serum-1 2 / Day 1 0h
01	N/A	2 / Day 1 0h	1401406 006	597067 117	2 347150	1	90 0	27	05104620000050	AA97220-01 05104620000050 01 N/A Serum-1 2 / Day 1 0h
01	N/A	2 / Day 1 0h	1488505 266	607745 786	2 449224	1	93 9	24	05104620000066	AA97220-01 05104620000066 01 N/A Serum-1 2 / Day 1 0h
01	N/A	3 / Day 1 0 05h	1734982 16	587057 548	2 955387	1	113	29	05104620000019	AA97220-01 05104620000019 01 N/A Serum-1 3 / Day 1 05h
01	N/A	3 / Day 1 0 05h	1410655 25	559919 769	2 519388	1	96 6	32	05104620000035	AA97220-01 05104620000035 01 N/A Serum-1 3 / Day 1 05h
01	N/A	3 / Day 1 0 05h	1194007 355	600789 082	1 987399	1	76 2	28	05104620000051	AA97220-01 05104620000051 01 N/A Serum-1 3 / Day 1 05h
01	N/A	3 / Day 1 0 05h	1610491 996	616446 642	2 612541	1	100	31	05104620000067	AA97220-01 05104620000067 01 N/A Serum-1 3 / Day 1 05h
01	N/A	4 / Day 1 0 0833h	1739183 053	574827 065	3 025576	1	116	34	05104620000020	AA97220-01 05104620000020 01 N/A Serum-1 4 / Day 1 0833h
01	N/A	4 / Day 1 0 0833h	1608426 834	617003 115	2 606837	1	100	33	05104620000036	AA97220-01 05104620000036 01 N/A Serum-1 4 / Day 1 0833h
01	N/A	4 / Day 1 0 0833h	1212897 341	575862 822	2 106226	1	80 8	36	05104620000052	AA97220-01 05104620000052 01 N/A Serum-1 4 / Day 1 0833h
01	N/A	4 / Day 1 0 0833h	1401030 403	556766 577	2 516369	1	96 5	35	05104620000068	AA97220-01 05104620000068 01 N/A Serum-1 4 / Day 1 0833h
01	N/A	5 / Day 1 0 125h	1931667 39	641830 27	3 009623	1	115	38	05104620000021	AA97220-01 05104620000021 01 N/A Serum-1 5 / Day 1 125h
01	N/A	5 / Day 1 0 125h	1392914 689	566651 708	2 458150	1	94 3	39	05104620000037	AA97220-01 05104620000037 01 N/A Serum-1 5 / Day 1 125h
01	N/A	5 / Day 1 0 125h	1303696 639	620416 411	2 101325	1	80 6	40	05104620000053	AA97220-01 05104620000053 01 N/A Serum-1 5 / Day 1 125h
01	N/A	5 / Day 1 0 125h	1570164 398	609875 282	2 574566	1	98 7	37	05104620000069	AA97220-01 05104620000069 01 N/A Serum-1 5 / Day 1 125h
01	N/A	6 / Day 1 0 1667h	1814958 676	624011 974	2 908532	1	112	45	05104620000022	AA97220-01 05104620000022 01 N/A Serum-1 6 / Day 1 1667h
01	N/A	6 / Day 1 0 1667h	1590222 618	624577 348	2 546078	1	97 7	44	05104620000038	AA97220-01 05104620000038 01 N/A Serum-1 6 / Day 1 1667h
01	N/A	6 / Day 1 0 1667h	1309038 281	646143 483	2 025925	1	77 7	42	05104620000054	AA97220-01 05104620000054 01 N/A Serum-1 6 / Day 1 1667h
01	N/A	6 / Day 1 0 1667h	1541528 954	596809 989	2 582948	1	99 1	43	05104620000070	AA97220-01 05104620000070 01 N/A Serum-1 6 / Day 1 1667h
01	N/A	7 / Day 1 0 25h	1157766 183	403908 54	2 866407	1	110	48	05104620000023	AA97220-01 05104620000023 01 N/A Serum-1 7 / Day 1 25h
01	N/A	7 / Day 1 0 25h	1695421 991	655191 99	2 587672	1	99 3	47	05104620000039	AA97220-01 05104620000039 01 N/A Serum-1 7 / Day 1 25h
01	N/A	7 / Day 1 0 25h	1431133 547	675923 08	2 117302	1	81 2	46	05104620000055	AA97220-01 05104620000055 01 N/A Serum-1 7 / Day 1 25h
01	N/A	7 / Day 1 0 25h	1850623 264	616509 606	3 001775	1	115	49	05104620000071	AA97220-01 05104620000071 01 N/A Serum-1 7 / Day 1 25h
01	N/A	8 / Day 1 0 333h	1896894 692	646802 765	2 932725	1	112	50	05104620000024	AA97220-01 05104620000024 01 N/A Serum-1 8 / Day 1 333h
01	N/A	8 / Day 1 0 333h	1821815 552	668148 922	2 726661	1	105	54	05104620000040	AA97220-01 05104620000040 01 N/A Serum-1 8 / Day 1 333h
01	N/A	8 / Day 1 0 333h	1222470 807	573945 368	2 129943	1	81 7	53	05104620000056	AA97220-01 05104620000056 01 N/A Serum-1 8 / Day 1 333h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
01	N/A	8 / Day 1 0 333h	1913523 002	639878 264	2 990449	1	115	51	05104620000072	AA97220-01 05104620000072 01 N/A Serum-1 8 / Day 1 333h
01	N/A	9 / Day 1 0 5h	1925043 351	662679 339	2 904939	1	111	56	05104620000025	AA97220-01 05104620000025 01 N/A Serum-1 9 / Day 1 5h
01	N/A	9 / Day 1 0 5h	1539107 561	558601 327	2 755288	1	106	55	05104620000041	AA97220-01 05104620000041 01 N/A Serum-1 9 / Day 1 5h
01	N/A	9 / Day 1 0 5h	1297367 588	655819 665	1 978238	1	75 9	57	05104620000057	AA97220-01 05104620000057 01 N/A Serum-1 9 / Day 1 5h
01	N/A	9 / Day 1 0 5h	1785699 18	611917 903	2 918201	1	112	58	05104620000073	AA97220-01 05104620000073 01 N/A Serum-1 9 / Day 1 5h
01	N/A	10 / Day 1 0 75h	1989150 499	624327 085	3 186071	1	122	61	05104620000026	AA97220-01 05104620000026 01 N/A Serum-1 10 / Day 1 75h
01	N/A	10 / Day 1 0 75h	1915976 504	654657 037	2 926687	1	112	60	05104620000042	AA97220-01 05104620000042 01 N/A Serum-1 10 / Day 1 75h
01	N/A	10 / Day 1 0 75h	1343030 354	615098 846	2 183438	1	83 7	59	05104620000058	AA97220-01 05104620000058 01 N/A Serum-1 10 / Day 1 75h
01	N/A	10 / Day 1 0 75h	1753641 859	591283 338	2 965823	1	114	62	05104620000074	AA97220-01 05104620000074 01 N/A Serum-1 10 / Day 1 75h
01	N/A	11 / Day 1 1h	1956702 27	658562 098	2 971174	1	114	64	05104620000027	AA97220-01 05104620000027 01 N/A Serum-1 11 / Day 1 1h
01	N/A	11 / Day 1 1h	1686312 73	593089 882	2 843267	1	109	67	05104620000043	AA97220-01 05104620000043 01 N/A Serum-1 11 / Day 1 1h
01	N/A	11 / Day 1 1h	1409179 015	627207 417	2 246751	1	86 2	66	05104620000059	AA97220-01 05104620000059 01 N/A Serum-1 11 / Day 1 1h
01	N/A	11 / Day 1 1h	2122993 539	659100 847	3 221045	1	124	65	05104620000075	AA97220-01 05104620000075 01 N/A Serum-1 11 / Day 1 1h
01	N/A	12 / Day 1 1 25h	1934968 207	670415 146	2 886224	1	111	69	05104620000028	AA97220-01 05104620000028 01 N/A Serum-1 12 / Day 1 1 25h
01	N/A	12 / Day 1 1 25h	1704782 581	606753 515	2 809679	1	108	68	05104620000044	AA97220-01 05104620000044 01 N/A Serum-1 12 / Day 1 1 25h
01	N/A	12 / Day 1 1 25h	1402710 579	619161 033	2 265502	1	86 9	71	05104620000060	AA97220-01 05104620000060 01 N/A Serum-1 12 / Day 1 1 25h
01	N/A	12 / Day 1 1 25h	1916990 891	612039 991	3 132133	1	120	70	05104620000076	AA97220-01 05104620000076 01 N/A Serum-1 12 / Day 1 1 25h
01	N/A	13 / Day 1 1 5h	1900159 845	634994 95	2 992402	1	115	72	05104620000029	AA97220-01 05104620000029 01 N/A Serum-1 13 / Day 1 1 5h
01	N/A	13 / Day 1 1 5h	1617860 383	585373 05	2 763811	1	106	76	05104620000045	AA97220-01 05104620000045 01 N/A Serum-1 13 / Day 1 1 5h
01	N/A	13 / Day 1 1 5h	1329331 329	605452 804	2 195599	1	84 2	73	05104620000061	AA97220-01 05104620000061 01 N/A Serum-1 13 / Day 1 1 5h
01	N/A	13 / Day 1 1 5h	1740247 648	540424 401	3 220150	1	124	75	05104620000077	AA97220-01 05104620000077 01 N/A Serum-1 13 / Day 1 1 5h
01	N/A	14 / Day 1 2h	1669278 511	570523 577	2 925871	1	112	78	05104620000030	AA97220-01 05104620000030 01 N/A Serum-1 14 / Day 1 2h
01	N/A	14 / Day 1 2h	1508366 697	590940 1	2 552487	1	97 9	79	05104620000046	AA97220-01 05104620000046 01 N/A Serum-1 14 / Day 1 2h
01	N/A	14 / Day 1 2h	1411176 908	651817 889	2 164986	1	83 0	77	05104620000062	AA97220-01 05104620000062 01 N/A Serum-1 14 / Day 1 2h
01	N/A	14 / Day 1 2h	1804974 657	603892 451	2 988901	1	115	80	05104620000078	AA97220-01 05104620000078 01 N/A Serum-1 14 / Day 1 2h
01	N/A	15 / Day 1 2 5h	1637483 558	591133 643	2 770073	1	106	81	05104620000031	AA97220-01 05104620000031 01 N/A Serum-1 15 / Day 1 2 5h
01	N/A	15 / Day 1 2 5h	737297 931	280153 674	*2 631762	1	*101	84	05104620000047	AA97220-01 05104620000047 01 N/A Serum-1 15 / Day 1 2 5h
01	N/A	15 / Day 1 2 5h	1262377 474	623413 389	2 024944	1	77 6	83	05104620000063	AA97220-01 05104620000063 01 N/A Serum-1 15 / Day 1 2 5h
01	N/A	15 / Day 1 2 5h	1901138 912	603271 552	3 151382	1	121	82	05104620000079	AA97220-01 05104620000079 01 N/A Serum-1 15 / Day 1 2 5h
01	N/A	16 / Day 1 3h	1473870 047	567988 257	2 594895	1	99 5	85	05104620000032	AA97220-01 05104620000032 01 N/A Serum-1 16 / Day 1 3h
01	N/A	16 / Day 1 3h	1389883 895	574714 421	2 418390	1	92 8	87	05104620000048	AA97220-01 05104620000048 01 N/A Serum-1 16 / Day 1 3h
01	N/A	16 / Day 1 3h	1091939 282	572325 516	1 907899	1	73 2	88	05104620000064	AA97220-01 05104620000064 01 N/A Serum-1 16 / Day 1 3h
01	N/A	16 / Day 1 3h	1623267 29	562213 913	2 887277	1	111	86	05104620000080	AA97220-01 05104620000080 01 N/A Serum-1 16 / Day 1 3h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1.00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

* - Sample Rejected

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 2
 Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		0	531832 725	0 000000	-0 181		-0 181	0 0
9	0 00		0	494627 164	0 000000	-0 181			
10	1 00	1 00000	15507 142	499958 162	0 031017	0 982	-1 8		
11	2 00	0 250000	33534 222	550819 122	0 060881	2 10	5 0		
12	4 00	0 0625000	46508 379	426710 681	0 108993	3 91	-2 3		
13	8 00	0 0156250	108808 413	500558 455	0 217374	7 97	-0 4		
14	16 0	0 00390625	232771 654	545895 743	0 426403	15 8	-1 3		
15	40 0	0 000625000	580752 492	552568 202	1 051006	39 2	-2 0		
16	80 0	0 000156250	1042296 418	488392 912	2 134135	79 8	-0 3		
17	160	0 0000390625	2302511 23	519820 775	4 429433	166	3 8		
18	200	0 0000250000	2949959 912	557787 082	5 288685	198	-1 0		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:
 Slope = 0 0266682459
 Intercept = 0 00482954985
 R-Squared = 0 9991

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)
 AAR - Concentration Found is Greater than 200 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 2
Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	2640431 17	498843 923	5 293101	1	198		198		1 1
2	0 00	2659623 395	497103 909	5 350236	1	200				
3	0 00	2578691 018	490402 588	5 258314	1	197				
4	0 00	2584853 339	486469 167	5 313499	1	199				
5	0 00	2684350 668	503548 22	5 330871	1	200				
91	0 00	2276535 525	439113 475	5 184390	1	194				
92	0 00	2268468 23	433240 105	5 236053	1	196				
30	3 00	38435 545	489548 376	0 078512	1	2 76	-8 0	2 74	-8 7	1 0
63	3 00	41120 43	530867 325	0 077459	1	2 72	-9 3			
41	37 5	531671 567	532697 695	0 998074	1	37 2	-0 8	37 7	0 5	1 9
74	37 5	423546 097	413870 857	1 023377	1	38 2	1 9			
52	150	2088037 865	527731 453	3 956630	1	148	-1 3	145	-3 3	2 9
89	150	1586211 989	419280 851	3 783173	1	142	-5 3			

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)
AAR - Concentration Found is Greater than 200 (Highest Standard)

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 2
Serum, Concentration of Cotinine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
01	N/A	1 / Day 1 - 0 0333h	1642455 209	540225 5	3 040314	1	114	20	05104620000001	AA97220-01 05104620000001 01 N/A Serum-1 1 / Day 1 - 0333h
01	N/A	2 / Day 1 0h	1652491 099	547025 124	3 020869	1	113	21	05104620000002	AA97220-01 05104620000002 01 N/A Serum-1 2 / Day 1 0h
01	N/A	3 / Day 1 0 05h	1515237 164	508982 845	2 976991	1	111	22	05104620000003	AA97220-01 05104620000003 01 N/A Serum-1 3 / Day 1 05h
01	N/A	4 / Day 1 0 0833h	1431955 62	522058 593	2 742902	1	103	23	05104620000004	AA97220-01 05104620000004 01 N/A Serum-1 4 / Day 1 0833h
01	N/A	5 / Day 1 0 125h	1419181 911	508695 28	2 789847	1	104	24	05104620000005	AA97220-01 05104620000005 01 N/A Serum-1 5 / Day 1 125h
01	N/A	6 / Day 1 0 1667h	1672611 899	565127 265	2 959708	1	111	25	05104620000006	AA97220-01 05104620000006 01 N/A Serum-1 6 / Day 1 1667h
01	N/A	7 / Day 1 0 25h	1418920 45	513260 305	2 764524	1	103	26	05104620000007	AA97220-01 05104620000007 01 N/A Serum-1 7 / Day 1 25h
01	N/A	8 / Day 1 0 333h	1610596 723	547175 277	2 943475	1	110	27	05104620000008	AA97220-01 05104620000008 01 N/A Serum-1 8 / Day 1 333h
01	N/A	9 / Day 1 0 5h	1583789 094	495655 424	3 195343	1	120	28	05104620000009	AA97220-01 05104620000009 01 N/A Serum-1 9 / Day 1 5h
01	N/A	10 / Day 1 0 75h	1666081 341	568164 574	2 932392	1	110	29	05104620000010	AA97220-01 05104620000010 01 N/A Serum-1 10 / Day 1 75h
01	N/A	11 / Day 1 1h	1593560 25	448852 504	3 550298	1	133	31	05104620000011	AA97220-01 05104620000011 01 N/A Serum-1 11 / Day 1 1h
01	N/A	12 / Day 1 1 25h	1955371 265	556803 413	3 511780	1	132	32	05104620000012	AA97220-01 05104620000012 01 N/A Serum-1 12 / Day 1 1 25h
01	N/A	13 / Day 1 1 5h	1614979 575	502840 469	3 211714	1	120	33	05104620000013	AA97220-01 05104620000013 01 N/A Serum-1 13 / Day 1 1 5h
01	N/A	14 / Day 1 2h	1792984 432	542374 21	3 305807	1	124	34	05104620000014	AA97220-01 05104620000014 01 N/A Serum-1 14 / Day 1 2h
01	N/A	15 / Day 1 2 5h	1690808 123	541193 73	3 124220	1	117	35	05104620000015	AA97220-01 05104620000015 01 N/A Serum-1 15 / Day 1 2 5h
01	N/A	16 / Day 1 3h	1612996 084	505242 577	3 192518	1	120	36	05104620000016	AA97220-01 05104620000016 01 N/A Serum-1 16 / Day 1 3h
02	N/A	1 / Day 1 - 0 0333h	1557940 191	479790 214	3 247128	1	122	39	05104620000113	AA97220-01 05104620000113 02 N/A Serum-1 1 / Day 1 - 0333h
02	N/A	1 / Day 1 - 0 0333h	1197135 379	471250 517	2 540338	1	95 1	37	05104620000129	AA97220-01 05104620000129 02 N/A Serum-1 1 / Day 1 - 0333h
02	N/A	1 / Day 1 - 0 0333h	1273211 633	484417 607	2 628335	1	98 4	38	05104620000145	AA97220-01 05104620000145 02 N/A Serum-1 1 / Day 1 - 0333h
02	N/A	2 / Day 1 0h	1664124 987	523765 932	3 177230	1	119	43	05104620000114	AA97220-01 05104620000114 02 N/A Serum-1 2 / Day 1 0h
02	N/A	2 / Day 1 0h	1097694 362	441176 189	2 488109	1	93 1	42	05104620000130	AA97220-01 05104620000130 02 N/A Serum-1 2 / Day 1 0h
02	N/A	2 / Day 1 0h	1175448 242	445760 885	2 636948	1	98 7	40	05104620000146	AA97220-01 05104620000146 02 N/A Serum-1 2 / Day 1 0h
02	N/A	3 / Day 1 0 05h	1449124 579	462944 174	3 130236	1	117	44	05104620000115	AA97220-01 05104620000115 02 N/A Serum-1 3 / Day 1 05h
02	N/A	3 / Day 1 0 05h	1219353 125	493127 778	2 472692	1	92 5	46	05104620000131	AA97220-01 05104620000131 02 N/A Serum-1 3 / Day 1 05h
02	N/A	3 / Day 1 0 05h	1459728 125	537673 829	2 714895	1	102	45	05104620000147	AA97220-01 05104620000147 02 N/A Serum-1 3 / Day 1 05h
02	N/A	4 / Day 1 0 0833h	1791127 23	584534 189	3 064196	1	115	47	05104620000116	AA97220-01 05104620000116 02 N/A Serum-1 4 / Day 1 0833h
02	N/A	4 / Day 1 0 0833h	1335632 014	528943 881	2 525092	1	94 5	48	05104620000132	AA97220-01 05104620000132 02 N/A Serum-1 4 / Day 1 0833h
02	N/A	4 / Day 1 0 0833h	1151369 302	414721 225	2 776249	1	104	49	05104620000148	AA97220-01 05104620000148 02 N/A Serum-1 4 / Day 1 0833h
02	N/A	5 / Day 1 0 125h	1490847 866	490229 012	3 041125	1	114	53	05104620000117	AA97220-01 05104620000117 02 N/A Serum-1 5 / Day 1 125h
02	N/A	5 / Day 1 0 125h	1293685 613	540096 342	2 395287	1	89 6	50	05104620000133	AA97220-01 05104620000133 02 N/A Serum-1 5 / Day 1 125h
02	N/A	5 / Day 1 0 125h	1414531 125	478790 45	2 954385	1	111	51	05104620000149	AA97220-01 05104620000149 02 N/A Serum-1 5 / Day 1 125h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
02	N/A	6 / Day 1 0 1667h	1347998 04	450935 087	2 989339	1	112	56	05104620000118	AA97220-01 05104620000118 02 N/A Serum-1 6 / Day 1 1667h
02	N/A	6 / Day 1 0 1667h	1054172 322	441539 863	2 387491	1	89 3	55	05104620000134	AA97220-01 05104620000134 02 N/A Serum-1 6 / Day 1 1667h
02	N/A	6 / Day 1 0 1667h	1190071 451	431430 457	2 758432	1	103	54	05104620000150	AA97220-01 05104620000150 02 N/A Serum-1 6 / Day 1 1667h
02	N/A	7 / Day 1 0 25h	1369588 792	443095 993	3 090953	1	116	58	05104620000119	AA97220-01 05104620000119 02 N/A Serum-1 7 / Day 1 25h
02	N/A	7 / Day 1 0 25h	1103023 746	451076 916	2 445312	1	91 5	59	05104620000135	AA97220-01 05104620000135 02 N/A Serum-1 7 / Day 1 25h
02	N/A	7 / Day 1 0 25h	1425680 863	506452 009	2 815036	1	105	57	05104620000151	AA97220-01 05104620000151 02 N/A Serum-1 7 / Day 1 25h
02	N/A	8 / Day 1 0 333h	1597555 197	534877 454	2 986769	1	112	61	05104620000120	AA97220-01 05104620000120 02 N/A Serum-1 8 / Day 1 333h
02	N/A	8 / Day 1 0 333h	1166584 56	484428 405	2 408167	1	90 1	60	05104620000136	AA97220-01 05104620000136 02 N/A Serum-1 8 / Day 1 333h
02	N/A	8 / Day 1 0 333h	1368228 634	469096 24	2 916733	1	109	62	05104620000152	AA97220-01 05104620000152 02 N/A Serum-1 8 / Day 1 333h
02	N/A	9 / Day 1 0 5h	1410151 094	454936 682	3 099665	1	116	64	05104620000121	AA97220-01 05104620000121 02 N/A Serum-1 9 / Day 1 5h
02	N/A	9 / Day 1 0 5h	1123812 993	434336 876	2 587422	1	96 8	66	05104620000137	AA97220-01 05104620000137 02 N/A Serum-1 9 / Day 1 5h
02	N/A	9 / Day 1 0 5h	1517220 846	495938 848	3 059290	1	115	65	05104620000153	AA97220-01 05104620000153 02 N/A Serum-1 9 / Day 1 5h
02	N/A	10 / Day 1 0 75h	1264536 836	385336 108	3 281646	1	123	68	05104620000122	AA97220-01 05104620000122 02 N/A Serum-1 10 / Day 1 75h
02	N/A	10 / Day 1 0 75h	1331686 93	510132 241	2 610474	1	97 7	69	05104620000138	AA97220-01 05104620000138 02 N/A Serum-1 10 / Day 1 75h
02	N/A	10 / Day 1 0 75h	1327023 304	455384 69	2 914071	1	109	67	05104620000154	AA97220-01 05104620000154 02 N/A Serum-1 10 / Day 1 75h
02	N/A	11 / Day 1 1h	1326156 909	402661 684	3 293477	1	123	70	05104620000123	AA97220-01 05104620000123 02 N/A Serum-1 11 / Day 1 1h
02	N/A	11 / Day 1 1h	1190497 881	467601 43	2 545967	1	95 3	72	05104620000139	AA97220-01 05104620000139 02 N/A Serum-1 11 / Day 1 1h
02	N/A	11 / Day 1 1h	1447857 801	487536 813	2 969740	1	111	71	05104620000155	AA97220-01 05104620000155 02 N/A Serum-1 11 / Day 1 1h
02	N/A	12 / Day 1 1 25h	1501689 693	442124 033	3 396535	1	127	76	05104620000124	AA97220-01 05104620000124 02 N/A Serum-1 12 / Day 1 1 25h
02	N/A	12 / Day 1 1 25h	1256435 147	475041 227	2 644897	1	99 0	73	05104620000140	AA97220-01 05104620000140 02 N/A Serum-1 12 / Day 1 1 25h
02	N/A	12 / Day 1 1 25h	1313549 112	481858 865	2 726004	1	102	75	05104620000156	AA97220-01 05104620000156 02 N/A Serum-1 12 / Day 1 1 25h
02	N/A	13 / Day 1 1 5h	1479729 761	427249 193	3 463388	1	130	77	05104620000125	AA97220-01 05104620000125 02 N/A Serum-1 13 / Day 1 1 5h
02	N/A	13 / Day 1 1 5h	1199971 338	458301 748	2 618300	1	98 0	78	05104620000141	AA97220-01 05104620000141 02 N/A Serum-1 13 / Day 1 1 5h
02	N/A	13 / Day 1 1 5h	1198117 39	424278 31	2 823895	1	106	79	05104620000157	AA97220-01 05104620000157 02 N/A Serum-1 13 / Day 1 1 5h
02	N/A	14 / Day 1 2h	1369980 559	419664 702	3 264465	1	122	82	05104620000126	AA97220-01 05104620000126 02 N/A Serum-1 14 / Day 1 2h
02	N/A	14 / Day 1 2h	1116484 927	427267 201	2 613084	1	97 8	80	05104620000142	AA97220-01 05104620000142 02 N/A Serum-1 14 / Day 1 2h
02	N/A	14 / Day 1 2h	1231733 304	445305 573	2 766041	1	104	81	05104620000158	AA97220-01 05104620000158 02 N/A Serum-1 14 / Day 1 2h
02	N/A	15 / Day 1 2 5h	1649399 711	499351 882	3 303081	1	124	84	05104620000127	AA97220-01 05104620000127 02 N/A Serum-1 15 / Day 1 2 5h
02	N/A	15 / Day 1 2 5h	1130485 818	456930 058	2 474089	1	92 6	83	05104620000143	AA97220-01 05104620000143 02 N/A Serum-1 15 / Day 1 2 5h
02	N/A	15 / Day 1 2 5h	1258433 176	438078 807	2 872618	1	108	85	05104620000159	AA97220-01 05104620000159 02 N/A Serum-1 15 / Day 1 2 5h
02	N/A	16 / Day 1 3h	1433077 571	436776 89	3 281029	1	123	87	05104620000128	AA97220-01 05104620000128 02 N/A Serum-1 16 / Day 1 3h
02	N/A	16 / Day 1 3h	977185 608	414082 257	2 359883	1	88 3	88	05104620000144	AA97220-01 05104620000144 02 N/A Serum-1 16 / Day 1 3h
02	N/A	16 / Day 1 3h	1266746 911	465420 695	2 721725	1	102	86	05104620000160	AA97220-01 05104620000160 02 N/A Serum-1 16 / Day 1 3h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1.00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 3
Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		1866 465	1805697 046	0 001034	0 0418		0 0267	80 1
9	0 00		1349 012	1694549 491	0 000796	0 0115			
10	1 00	1 00000	13884 045	1700089 719	0 008167	0 953	-4 7		
11	2 00	0 250000	28157 357	1600182 202	0 017596	2 16	8 0		
12	4 00	0 0625000	57209 748	1715962 707	0 033340	4 17	4 3		
13	8 00	0 0156250	107569 318	1721777 458	0 062476	7 89	-1 4		
14	16 0	0 00390625	214613 068	1693580 336	0 126722	16 1	0 6		
15	40 0	0 000625000	508798 861	1655410 41	0 307355	39 2	-2 0		
16	80 0	0 000156250	1146759 712	1846211 464	0 621142	79 2	-1 0		
17	160	0 0000390625	1988133 636	1610015 515	1 234854	158	-1 3		
18	200	0 0000250000	2710663 535	1762187 725	1 538238	196	-2 0		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:

Slope = 0 00783155364

Intercept = 0 000706265426

R-Squared = 0 9981

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 3
Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	2484314 212	1628938 994	1 525112	1	195		195		1 4
2	0 00	2613890 569	1690004 793	1 546676	1	197				
3	0 00	2599540 014	1670210 597	1 556415	1	199				
4	0 00	2734053 698	1810209 355	1 510352	1	193				
5	0 00	2706888 948	1770117 438	1 529214	1	195				
89	0 00	2882301 187	1902285 583	1 515178	1	193				
90	0 00	2958552 182	1981073 191	1 493409	1	191				
30	3 00	37287 281	1719286 538	0 021688	1	2 68	-10 7	2 78	-7 3	4 8
63	3 00	37229 862	1607278 256	0 023163	1	2 87	-4 3			
41	37 5	414164 932	1526469 435	0 271322	1	34 6	-7 7	35 0	-6 7	1 6
74	37 5	490266 791	1764277 847	0 277885	1	35 4	-5 6			
52	150	1366493 487	1260755 779	1 083869	1	138	-8 0	137	-8 7	1 0
87	150	1988788 985	1862815 665	1 067625	1	136	-9 3			

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)
AAR - Concentration Found is Greater than 200 (Highest Standard)

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 3
Serum, Concentration of Cotinine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
02	N/A	1 / Day 1 -0 0333h	1637939 986	1874360 045	0 873866	1	111	20	05104620000081	AA97220-01 05104620000081 02 N/A Serum-1 1 / Day 1 - 0333h
02	N/A	1 / Day 1 -0 0333h	1669181 785	1840094 733	0 907117	1	116	21	05104620000097	AA97220-01 05104620000097 02 N/A Serum-1 1 / Day 1 - 0333h
02	N/A	2 / Day 1 0h	1607030 413	1886682 068	0 851776	1	109	22	05104620000082	AA97220-01 05104620000082 02 N/A Serum-1 2 / Day 1 0h
02	N/A	2 / Day 1 0h	1649694 236	1852790 656	0 890384	1	114	23	05104620000098	AA97220-01 05104620000098 02 N/A Serum-1 2 / Day 1 0h
02	N/A	3 / Day 1 0 05h	1357545 718	1617628 017	0 839220	1	107	25	05104620000083	AA97220-01 05104620000083 02 N/A Serum-1 3 / Day 1 05h
02	N/A	3 / Day 1 0 05h	1575749 61	1780853 361	0 884828	1	113	24	05104620000099	AA97220-01 05104620000099 02 N/A Serum-1 3 / Day 1 05h
02	N/A	4 / Day 1 0 0833h	1317079 863	1615210 131	0 815423	1	104	27	05104620000084	AA97220-01 05104620000084 02 N/A Serum-1 4 / Day 1 0833h
02	N/A	4 / Day 1 0 0833h	1529697 109	1667065 231	0 917599	1	117	26	05104620000100	AA97220-01 05104620000100 02 N/A Serum-1 4 / Day 1 0833h
02	N/A	5 / Day 1 0 125h	1471065 427	1754384 092	0 838508	1	107	29	05104620000085	AA97220-01 05104620000085 02 N/A Serum-1 5 / Day 1 125h
02	N/A	5 / Day 1 0 125h	1521257 503	1708186 604	0 890569	1	114	28	05104620000101	AA97220-01 05104620000101 02 N/A Serum-1 5 / Day 1 125h
02	N/A	6 / Day 1 0 1667h	1346608 26	1641515 152	0 820345	1	105	31	05104620000086	AA97220-01 05104620000086 02 N/A Serum-1 6 / Day 1 1667h
02	N/A	6 / Day 1 0 1667h	1525140 92	1734774 964	0 879158	1	112	32	05104620000102	AA97220-01 05104620000102 02 N/A Serum-1 6 / Day 1 1667h
02	N/A	7 / Day 1 0 25h	1400214 067	1671667 601	0 837615	1	107	34	05104620000087	AA97220-01 05104620000087 02 N/A Serum-1 7 / Day 1 25h
02	N/A	7 / Day 1 0 25h	1451757 542	1683772 688	0 862205	1	110	33	05104620000103	AA97220-01 05104620000103 02 N/A Serum-1 7 / Day 1 25h
02	N/A	8 / Day 1 0 333h	1469724 737	1738369 977	0 845461	1	108	36	05104620000088	AA97220-01 05104620000088 02 N/A Serum-1 8 / Day 1 333h
02	N/A	8 / Day 1 0 333h	1468499 569	1641841 304	0 894422	1	114	35	05104620000104	AA97220-01 05104620000104 02 N/A Serum-1 8 / Day 1 333h
02	N/A	9 / Day 1 0 5h	1383625 525	1679242 472	0 823958	1	105	38	05104620000089	AA97220-01 05104620000089 02 N/A Serum-1 9 / Day 1 5h
02	N/A	9 / Day 1 0 5h	1465833 708	1584818 699	0 924922	1	118	37	05104620000105	AA97220-01 05104620000105 02 N/A Serum-1 9 / Day 1 5h
02	N/A	10 / Day 1 0 75h	1393548 093	1674384 557	0 832275	1	106	40	05104620000090	AA97220-01 05104620000090 02 N/A Serum-1 10 / Day 1 75h
02	N/A	10 / Day 1 0 75h	1539683 925	1502828 331	1 024524	1	131	39	05104620000106	AA97220-01 05104620000106 02 N/A Serum-1 10 / Day 1 75h
02	N/A	11 / Day 1 1h	1441313 801	1615945 045	0 891932	1	114	42	05104620000091	AA97220-01 05104620000091 02 N/A Serum-1 11 / Day 1 1h
02	N/A	11 / Day 1 1h	1631522 223	1510961 663	1 079791	1	138	43	05104620000107	AA97220-01 05104620000107 02 N/A Serum-1 11 / Day 1 1h
02	N/A	12 / Day 1 1 25h	1320841 138	1534290 916	0 860881	1	110	44	05104620000092	AA97220-01 05104620000092 02 N/A Serum-1 12 / Day 1 1 25h
02	N/A	12 / Day 1 1 25h	1613247 178	1500690 498	1 075003	1	137	45	05104620000108	AA97220-01 05104620000108 02 N/A Serum-1 12 / Day 1 1 25h
02	N/A	13 / Day 1 1 5h	1284186 587	1502601 715	0 854642	1	109	47	05104620000093	AA97220-01 05104620000093 02 N/A Serum-1 13 / Day 1 1 5h
02	N/A	13 / Day 1 1 5h	1559206 414	1451338 352	1 074323	1	137	46	05104620000109	AA97220-01 05104620000109 02 N/A Serum-1 13 / Day 1 1 5h
02	N/A	14 / Day 1 2h	1287369 112	1433868 322	0 897829	1	115	49	05104620000094	AA97220-01 05104620000094 02 N/A Serum-1 14 / Day 1 2h
02	N/A	14 / Day 1 2h	1467430 343	1339914 816	1 095167	1	140	48	05104620000110	AA97220-01 05104620000110 02 N/A Serum-1 14 / Day 1 2h
02	N/A	15 / Day 1 2 5h	1289575 443	1449355 715	0 889758	1	114	50	05104620000095	AA97220-01 05104620000095 02 N/A Serum-1 15 / Day 1 2 5h
02	N/A	15 / Day 1 2 5h	1419628 24	1375314 879	1 032221	1	132	51	05104620000111	AA97220-01 05104620000111 02 N/A Serum-1 15 / Day 1 2 5h
02	N/A	16 / Day 1 3h	1356686 847	1582624 676	0 857239	1	109	54	05104620000096	AA97220-01 05104620000096 02 N/A Serum-1 16 / Day 1 3h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
02	N/A	16 / Day 1 3h	1526142 745	1563585 674	0 976053	1	125	53	05104620000112	AA97220-01 05104620000112 02 N/A Serum-1 16 / Day 1 3h
03	N/A	1 / Day 1 -0 0333h	3132471 376	1691446 327	*1 851948	1	*AAR>(200)	55	05104620000209	AA97220-01 05104620000209 03 N/A Serum-1 1 / Day 1 - 0333h
03	N/A	1 / Day 1 -0 0333h	3722816 615	1729325 537	*2 152756	1	*AAR>(200)	56	05104620000225	AA97220-01 05104620000225 03 N/A Serum-1 1 / Day 1 - 0333h
03	N/A	2 / Day 1 0h	2981718 537	1648030 781	*1 809261	1	*AAR>(200)	57	05104620000210	AA97220-01 05104620000210 03 N/A Serum-1 2 / Day 1 0h
03	N/A	2 / Day 1 0h	3326861 587	1603562 017	*2 074670	1	*AAR>(200)	58	05104620000226	AA97220-01 05104620000226 03 N/A Serum-1 2 / Day 1 0h
03	N/A	3 / Day 1 0 05h	3067952 511	1636512 966	*1 874689	1	*AAR>(200)	60	05104620000211	AA97220-01 05104620000211 03 N/A Serum-1 3 / Day 1 05h
03	N/A	3 / Day 1 0 05h	3337768 791	1558771 665	*2 141281	1	*AAR>(200)	59	05104620000227	AA97220-01 05104620000227 03 N/A Serum-1 3 / Day 1 05h
03	N/A	4 / Day 1 0 0833h	2953040 431	1602250 678	*1 843058	1	*AAR>(200)	62	05104620000212	AA97220-01 05104620000212 03 N/A Serum-1 4 / Day 1 0833h
03	N/A	4 / Day 1 0 0833h	3715286 732	1689387 186	*2 199192	1	*AAR>(200)	61	05104620000228	AA97220-01 05104620000228 03 N/A Serum-1 4 / Day 1 0833h
03	N/A	5 / Day 1 0 125h	3081925 447	1619396 823	*1 903132	1	*AAR>(200)	64	05104620000213	AA97220-01 05104620000213 03 N/A Serum-1 5 / Day 1 125h
03	N/A	6 / Day 1 0 1667h	2905584 737	1564830 458	*1 856805	1	*AAR>(200)	65	05104620000214	AA97220-01 05104620000214 03 N/A Serum-1 6 / Day 1 1667h
03	N/A	7 / Day 1 0 25h	2962827 157	1603791 806	*1 847389	1	*AAR>(200)	66	05104620000215	AA97220-01 05104620000215 03 N/A Serum-1 7 / Day 1 25h
03	N/A	7 / Day 1 0 25h	3264761 849	1529091 556	*2 135099	1	*AAR>(200)	67	05104620000231	AA97220-01 05104620000231 03 N/A Serum-1 7 / Day 1 25h
03	N/A	8 / Day 1 0 333h	3078545 937	1639200 757	*1 878077	1	*AAR>(200)	69	05104620000216	AA97220-01 05104620000216 03 N/A Serum-1 8 / Day 1 333h
03	N/A	8 / Day 1 0 333h	3411216 946	1602290 27	*2 128963	1	*AAR>(200)	68	05104620000232	AA97220-01 05104620000232 03 N/A Serum-1 8 / Day 1 333h
03	N/A	9 / Day 1 0 5h	2891710 919	1555266 601	*1 859302	1	*AAR>(200)	71	05104620000217	AA97220-01 05104620000217 03 N/A Serum-1 9 / Day 1 5h
03	N/A	9 / Day 1 0 5h	3413818 601	1674527 586	*2 038676	1	*AAR>(200)	70	05104620000233	AA97220-01 05104620000233 03 N/A Serum-1 9 / Day 1 5h
03	N/A	10 / Day 1 0 75h	3373827 586	1723324 504	*1 957744	1	*AAR>(200)	73	05104620000218	AA97220-01 05104620000218 03 N/A Serum-1 10 / Day 1 75h
03	N/A	10 / Day 1 0 75h	3577265 64	1765975 2	*2 025660	1	*AAR>(200)	72	05104620000234	AA97220-01 05104620000234 03 N/A Serum-1 10 / Day 1 75h
03	N/A	11 / Day 1 1h	3083526 533	1695530 023	*1 818621	1	*AAR>(200)	76	05104620000219	AA97220-01 05104620000219 03 N/A Serum-1 11 / Day 1 1h
03	N/A	11 / Day 1 1h	3823746 125	1735669 061	*2 203039	1	*AAR>(200)	75	05104620000235	AA97220-01 05104620000235 03 N/A Serum-1 11 / Day 1 1h
03	N/A	12 / Day 1 1 25h	3066056 803	1724278 126	*1 778168	1	*AAR>(200)	77	05104620000220	AA97220-01 05104620000220 03 N/A Serum-1 12 / Day 1 1 25h
03	N/A	12 / Day 1 1 25h	3780158 372	1771462 248	*2 133920	1	*AAR>(200)	78	05104620000236	AA97220-01 05104620000236 03 N/A Serum-1 12 / Day 1 1 25h
03	N/A	13 / Day 1 1 5h	3348320 314	1829328 671	*1 830355	1	*AAR>(200)	80	05104620000221	AA97220-01 05104620000221 03 N/A Serum-1 13 / Day 1 1 5h
03	N/A	13 / Day 1 1 5h	3815641 788	1864370 675	*2 046611	1	*AAR>(200)	79	05104620000237	AA97220-01 05104620000237 03 N/A Serum-1 13 / Day 1 1 5h
03	N/A	14 / Day 1 2h	3810630 513	2025509 624	*1 881319	1	*AAR>(200)	82	05104620000222	AA97220-01 05104620000222 03 N/A Serum-1 14 / Day 1 2h
03	N/A	14 / Day 1 2h	3660962 64	1750133 714	*2 091819	1	*AAR>(200)	81	05104620000238	AA97220-01 05104620000238 03 N/A Serum-1 14 / Day 1 2h
03	N/A	15 / Day 1 2 5h	3606218 452	2006668 627	*1 797117	1	*AAR>(200)	84	05104620000223	AA97220-01 05104620000223 03 N/A Serum-1 15 / Day 1 2 5h
03	N/A	15 / Day 1 2 5h	3956617 856	1918384 501	*2 062474	1	*AAR>(200)	83	05104620000239	AA97220-01 05104620000239 03 N/A Serum-1 15 / Day 1 2 5h
03	N/A	16 / Day 1 3h	3414842 089	1913009 467	*1 785063	1	*AAR>(200)	86	05104620000224	AA97220-01 05104620000224 03 N/A Serum-1 16 / Day 1 3h
03	N/A	16 / Day 1 3h	4081790 941	2104741 098	*1 939332	1	*AAR>(200)	85	05104620000240	AA97220-01 05104620000240 03 N/A Serum-1 16 / Day 1 3h

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

* - Sample Rejected

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 4
Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		962 878	1513881 145	0 000636	0 0817		0 0862	7 3
9	0 00		1022 612	1451228 057	0 000705	0 0906			
10	1 00	1 00000	12028 748	1635331 598	0 007356	0 951	-4 9		
11	2 00	0 250000	30301 983	1794037 252	0 016890	2 18	9 0		
12	4 00	0 0625000	51029 368	1643465 692	0 031050	4 02	0 5		
13	8 00	0 0156250	113840 346	1798153 033	0 063310	8 19	2 4		
14	16 0	0 00390625	200210 948	1645550 592	0 121668	15 7	-1 9		
15	40 0	0 000625000	610148 052	2004531 87	0 304384	39 4	-1 5		
16	80 0	0 000156250	1153673 813	1873687 398	0 615724	79 7	-0 4		
17	160	0 0000390625	1949092 516	1567395 379	1 243523	161	0 6		
18	200	0 0000250000	2156972 697	1457353 249	1 480062	192	-4 0		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:

Slope = 0 00772786708

Intercept = 0 00000461928311

R-Squared = 0 9977

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 4
Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	2225748 35	1457021 851	1 527601	1	198		193		1 3
2	0 00	2607888 958	1735463 979	1 502704	1	194				
3	0 00	2546999 605	1738661 91	1 464919	1	190				
4	0 00	2122701 209	1409571 068	1 505920	1	195				
5	0 00	1872083 167	1262717 27	1 482583	1	192				
91	0 00	2375101 412	1602965 064	1 481693	1	192				
92	0 00	2496525 417	1674996 295	1 490466	1	193				
30	3 00	38769 242	1793773 099	0 021613	1	2 80	-6 7	2 82	-6 0	0 8
63	3 00	46995 473	2149171 35	0 021867	1	2 83	-5 7			
41	37 5	457819 979	1700945 501	0 269156	1	34 8	-7 2	35 1	-6 4	1 2
74	37 5	598114 982	2187965 825	0 273366	1	35 4	-5 6			
52	150	1634169 736	1491918 053	1 095348	1	142	-5 3	142	-5 3	0 5
89	150	1642471 728	1506383 83	1 090341	1	141	-6 0			

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)
AAR - Concentration Found is Greater than 200 (Highest Standard)

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 4
Serum, Concentration of Cotinine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
03	N/A	1 / Day 1 -0 0333h	3139379 04	1571283 676	*1 997971	1	*AAR>(200)	20	05104620000161	AA97220-01 05104620000161 03 N/A Serum-1 1 / Day 1 - 0333h
03	N/A	1 / Day 1 -0 0333h	3254931 341	1744585 322	*1 865734	1	*AAR>(200)	21	05104620000177	AA97220-01 05104620000177 03 N/A Serum-1 1 / Day 1 - 0333h
03	N/A	1 / Day 1 -0 0333h	2682913 239	1437526 915	*1 866339	1	*AAR>(200)	22	05104620000193	AA97220-01 05104620000193 03 N/A Serum-1 1 / Day 1 - 0333h
03	N/A	2 / Day 1 0h	2863916 657	1483472 797	*1 930549	1	*AAR>(200)	23	05104620000162	AA97220-01 05104620000162 03 N/A Serum-1 2 / Day 1 0h
03	N/A	2 / Day 1 0h	2876589 632	1570596 931	*1 831526	1	*AAR>(200)	24	05104620000178	AA97220-01 05104620000178 03 N/A Serum-1 2 / Day 1 0h
03	N/A	2 / Day 1 0h	2921703 653	1587932 286	*1 839942	1	*AAR>(200)	25	05104620000194	AA97220-01 05104620000194 03 N/A Serum-1 2 / Day 1 0h
03	N/A	3 / Day 1 0 05h	3305446 112	1744310 582	*1 894987	1	*AAR>(200)	26	05104620000163	AA97220-01 05104620000163 03 N/A Serum-1 3 / Day 1 05h
03	N/A	3 / Day 1 0 05h	3001633 264	1636775 457	*1 833870	1	*AAR>(200)	28	05104620000179	AA97220-01 05104620000179 03 N/A Serum-1 3 / Day 1 05h
03	N/A	3 / Day 1 0 05h	3042716 393	1689832 049	*1 800603	1	*AAR>(200)	27	05104620000195	AA97220-01 05104620000195 03 N/A Serum-1 3 / Day 1 05h
03	N/A	4 / Day 1 0 0833h	3074437 251	1634244 607	*1 881259	1	*AAR>(200)	32	05104620000164	AA97220-01 05104620000164 03 N/A Serum-1 4 / Day 1 0833h
03	N/A	4 / Day 1 0 0833h	2570409 838	1397998 31	*1 838636	1	*AAR>(200)	31	05104620000180	AA97220-01 05104620000180 03 N/A Serum-1 4 / Day 1 0833h
03	N/A	4 / Day 1 0 0833h	3025681 057	1641209 86	*1 843567	1	*AAR>(200)	29	05104620000196	AA97220-01 05104620000196 03 N/A Serum-1 4 / Day 1 0833h
03	N/A	5 / Day 1 0 125h	2730956 457	1378647 03	*1 980896	1	*AAR>(200)	35	05104620000165	AA97220-01 05104620000165 03 N/A Serum-1 5 / Day 1 125h
03	N/A	5 / Day 1 0 125h	2327913 678	1275406 005	*1 825233	1	*AAR>(200)	34	05104620000181	AA97220-01 05104620000181 03 N/A Serum-1 5 / Day 1 125h
03	N/A	5 / Day 1 0 125h	2602421 717	1402574 814	*1 855460	1	*AAR>(200)	33	05104620000197	AA97220-01 05104620000197 03 N/A Serum-1 5 / Day 1 125h
03	N/A	6 / Day 1 0 1667h	2758967 014	1461735 448	*1 887460	1	*AAR>(200)	36	05104620000166	AA97220-01 05104620000166 03 N/A Serum-1 6 / Day 1 1667h
03	N/A	6 / Day 1 0 1667h	3097104 789	1730483 639	*1 789734	1	*AAR>(200)	38	05104620000182	AA97220-01 05104620000182 03 N/A Serum-1 6 / Day 1 1667h
03	N/A	6 / Day 1 0 1667h	2490095 449	1382219 032	*1 801520	1	*AAR>(200)	37	05104620000198	AA97220-01 05104620000198 03 N/A Serum-1 6 / Day 1 1667h
03	N/A	7 / Day 1 0 25h	2815471 686	1503620 816	*1 872461	1	*AAR>(200)	39	05104620000167	AA97220-01 05104620000167 03 N/A Serum-1 7 / Day 1 25h
03	N/A	7 / Day 1 0 25h	2700347 388	1555614 436	*1 735872	1	*AAR>(200)	40	05104620000183	AA97220-01 05104620000183 03 N/A Serum-1 7 / Day 1 25h
03	N/A	7 / Day 1 0 25h	2653120 712	1522689 009	*1 742392	1	*AAR>(200)	42	05104620000199	AA97220-01 05104620000199 03 N/A Serum-1 7 / Day 1 25h
03	N/A	8 / Day 1 0 333h	2657897 118	1428533 436	*1 860577	1	*AAR>(200)	44	05104620000168	AA97220-01 05104620000168 03 N/A Serum-1 8 / Day 1 333h
03	N/A	8 / Day 1 0 333h	2561949 315	1449157 866	*1 767888	1	*AAR>(200)	43	05104620000184	AA97220-01 05104620000184 03 N/A Serum-1 8 / Day 1 333h
03	N/A	8 / Day 1 0 333h	2690960 752	1505240 218	*1 787728	1	*AAR>(200)	45	05104620000200	AA97220-01 05104620000200 03 N/A Serum-1 8 / Day 1 333h
03	N/A	9 / Day 1 0 5h	1945447 848	1041960 024	*1 867104	1	*AAR>(200)	48	05104620000169	AA97220-01 05104620000169 03 N/A Serum-1 9 / Day 1 5h
03	N/A	9 / Day 1 0 5h	2779549 527	1529506 365	*1 817285	1	*AAR>(200)	47	05104620000185	AA97220-01 05104620000185 03 N/A Serum-1 9 / Day 1 5h
03	N/A	9 / Day 1 0 5h	3205405 113	1788861 911	*1 791868	1	*AAR>(200)	46	05104620000201	AA97220-01 05104620000201 03 N/A Serum-1 9 / Day 1 5h
03	N/A	10 / Day 1 0 75h	2983112 751	1569217 38	*1 901019	1	*AAR>(200)	50	05104620000170	AA97220-01 05104620000170 03 N/A Serum-1 10 / Day 1 75h
03	N/A	10 / Day 1 0 75h	2884829 937	1605071 932	*1 797321	1	*AAR>(200)	51	05104620000186	AA97220-01 05104620000186 03 N/A Serum-1 10 / Day 1 75h
03	N/A	10 / Day 1 0 75h	2928478 836	1619096 744	*1 808711	1	*AAR>(200)	49	05104620000202	AA97220-01 05104620000202 03 N/A Serum-1 10 / Day 1 75h
03	N/A	11 / Day 1 1h	3611499 581	1909550 841	*1 891282	1	*AAR>(200)	54	05104620000171	AA97220-01 05104620000171 03 N/A Serum-1 11 / Day 1 1h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
03	N/A	11 / Day 1 1h	3061135 7	1742820 991	*1 756426	1	*AAR>(200)	55	05104620000187	AA97220-01 05104620000187 03 N/A Serum-1 11 / Day 1 1h
03	N/A	11 / Day 1 1h	3095461 561	1725372 86	*1 794083	1	*AAR>(200)	53	05104620000203	AA97220-01 05104620000203 03 N/A Serum-1 11 / Day 1 1h
03	N/A	12 / Day 1 1 25h	3272070 287	1791936 033	*1 825997	1	*AAR>(200)	57	05104620000172	AA97220-01 05104620000172 03 N/A Serum-1 12 / Day 1 1 25h
03	N/A	12 / Day 1 1 25h	3255927 928	1820435 84	*1 788543	1	*AAR>(200)	58	05104620000188	AA97220-01 05104620000188 03 N/A Serum-1 12 / Day 1 1 25h
03	N/A	12 / Day 1 1 25h	3020004 984	1703870 342	*1 772438	1	*AAR>(200)	56	05104620000204	AA97220-01 05104620000204 03 N/A Serum-1 12 / Day 1 1 25h
03	N/A	13 / Day 1 1 5h	3575265 255	1902927 784	*1 878823	1	*AAR>(200)	61	05104620000173	AA97220-01 05104620000173 03 N/A Serum-1 13 / Day 1 1 5h
03	N/A	13 / Day 1 1 5h	3203759 528	1770709 231	*1 809309	1	*AAR>(200)	59	05104620000189	AA97220-01 05104620000189 03 N/A Serum-1 13 / Day 1 1 5h
03	N/A	13 / Day 1 1 5h	3379333 428	1879727 384	*1 797778	1	*AAR>(200)	60	05104620000205	AA97220-01 05104620000205 03 N/A Serum-1 13 / Day 1 1 5h
03	N/A	14 / Day 1 2h	4078848 113	2228087 472	*1 830650	1	*AAR>(200)	62	05104620000174	AA97220-01 05104620000174 03 N/A Serum-1 14 / Day 1 2h
03	N/A	14 / Day 1 2h	3686036 036	2060743 077	*1 788693	1	*AAR>(200)	65	05104620000190	AA97220-01 05104620000190 03 N/A Serum-1 14 / Day 1 2h
03	N/A	14 / Day 1 2h	3161760 479	1773722 802	*1 782556	1	*AAR>(200)	64	05104620000206	AA97220-01 05104620000206 03 N/A Serum-1 14 / Day 1 2h
03	N/A	15 / Day 1 2 5h	3648448 354	1961392 285	*1 860132	1	*AAR>(200)	66	05104620000175	AA97220-01 05104620000175 03 N/A Serum-1 15 / Day 1 2 5h
03	N/A	15 / Day 1 2 5h	3592616 095	2104403 043	*1 707190	1	*AAR>(200)	67	05104620000191	AA97220-01 05104620000191 03 N/A Serum-1 15 / Day 1 2 5h
03	N/A	15 / Day 1 2 5h	3352167 764	1922781 959	*1 743395	1	*AAR>(200)	68	05104620000207	AA97220-01 05104620000207 03 N/A Serum-1 15 / Day 1 2 5h
03	N/A	16 / Day 1 3h	3665937 173	1989035 358	*1 843073	1	*AAR>(200)	69	05104620000176	AA97220-01 05104620000176 03 N/A Serum-1 16 / Day 1 3h
03	N/A	16 / Day 1 3h	2925649 46	1811199 764	*1 615310	1	*AAR>(200)	71	05104620000192	AA97220-01 05104620000192 03 N/A Serum-1 16 / Day 1 3h
03	N/A	16 / Day 1 3h	3166301 553	1836378 64	*1 724210	1	*AAR>(200)	70	05104620000208	AA97220-01 05104620000208 03 N/A Serum-1 16 / Day 1 3h
04	N/A	1 / Day 1 -0 0333h	1495944 295	1586671 144	0 942819	1	122	72	05104620000305	AA97220-01 05104620000305 04 N/A Serum-1 1 / Day 1 - 0333h
04	N/A	2 / Day 1 0h	1907704 271	2014154 366	0 947149	1	123	73	05104620000306	AA97220-01 05104620000306 04 N/A Serum-1 2 / Day 1 0h
04	N/A	3 / Day 1 0 05h	1881997 654	1859548 113	1 012073	1	131	75	05104620000307	AA97220-01 05104620000307 04 N/A Serum-1 3 / Day 1 05h
04	N/A	4 / Day 1 0 0833h	1914222 542	2021213 141	0 947066	1	123	76	05104620000308	AA97220-01 05104620000308 04 N/A Serum-1 4 / Day 1 0833h
04	N/A	5 / Day 1 0 125h	1933269 194	2017077 443	0 958451	1	124	77	05104620000309	AA97220-01 05104620000309 04 N/A Serum-1 5 / Day 1 125h
04	N/A	6 / Day 1 0 1667h	1971803 455	2012290 829	0 979880	1	127	78	05104620000310	AA97220-01 05104620000310 04 N/A Serum-1 6 / Day 1 1667h
04	N/A	7 / Day 1 0 25h	1703382 737	1617055 147	1 053386	1	136	79	05104620000311	AA97220-01 05104620000311 04 N/A Serum-1 7 / Day 1 25h
04	N/A	8 / Day 1 0 333h	1868828 887	1833282 5	1 019389	1	132	80	05104620000312	AA97220-01 05104620000312 04 N/A Serum-1 8 / Day 1 333h
04	N/A	9 / Day 1 0 5h	1360373 165	1356374 929	1 002948	1	130	81	05104620000313	AA97220-01 05104620000313 04 N/A Serum-1 9 / Day 1 5h
04	N/A	10 / Day 1 0 75h	700633 676	673805 428	*1 039816	1	*135	82	05104620000314	AA97220-01 05104620000314 04 N/A Serum-1 10 / Day 1 75h
04	N/A	11 / Day 1 1h	1343647 843	1305316 765	1 029365	1	133	83	05104620000315	AA97220-01 05104620000315 04 N/A Serum-1 11 / Day 1 1h
04	N/A	12 / Day 1 1 25h	1403152 699	1516379 53	0 925331	1	120	84	05104620000316	AA97220-01 05104620000316 04 N/A Serum-1 12 / Day 1 1 25h
04	N/A	13 / Day 1 1 5h	1681812 077	1706130 942	0 985746	1	128	85	05104620000317	AA97220-01 05104620000317 04 N/A Serum-1 13 / Day 1 1 5h
04	N/A	14 / Day 1 2h	1016755 837	1021927 043	0 994940	1	129	86	05104620000318	AA97220-01 05104620000318 04 N/A Serum-1 14 / Day 1 2h
04	N/A	15 / Day 1 2 5h	1499662 949	1509156 873	0 993709	1	129	87	05104620000319	AA97220-01 05104620000319 04 N/A Serum-1 15 / Day 1 2 5h
04	N/A	16 / Day 1 3h	1585181 414	1535211 213	1 032549	1	134	88	05104620000320	AA97220-01 05104620000320 04 N/A Serum-1 16 / Day 1 3h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1.00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

* - Sample Rejected

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 5
 Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		0	493011 366	0 000000	-0 0919		-0 0919	0 0
9	0 00		0	523717 183	0 000000	-0 0919			
10	1 00	1 00000	14532 663	532315 336	0 027301	0 925	-7 5		
11	2 00	0 250000	28506 631	455150 617	0 062631	2 24	12 0		
12	4 00	0 0625000	58217 592	492215 649	0 118277	4 32	8 0		
13	8 00	0 0156250	103892 455	493839 086	0 210377	7 75	-3 1		
14	16 0	0 00390625	198226 882	469539 242	0 422173	15 6	-2 5		
15	40 0	0 000625000	594991 667	546944 352	1 087847	40 4	1 0		
16	80 0	0 000156250	1273768 813	598937 952	2 126712	79 2	-1 0		
17	160	0 0000390625	1750430 793	422867 662	4 139429	154	-3 8		
18	200	0 0000250000	2200696 571	424803 362	5 180506	193	-3 5		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:

Slope = 0 0268358948

Intercept = 0 00246679451

R-Squared = 0 9949

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 5
Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	2264141 217	444976 332	5 088228	1	190		195		2 7
2	0 00	2111230 61	411379 823	5 132071	1	191				
3	0 00	2118137 419	408416 121	5 186224	1	193				
4	0 00	2108898 59	397895 368	5 300134	1	197				
5	0 00	1818438 668	348321 362	5 220578	1	194				
91	0 00	2449527 011	443747 07	5 520097	1	206				
92	0 00	1764602 129	337069 923	5 235122	1	195				
30	3 00	42212 158	533476 16	0 079127	1	2 86	-4 7	2 98	-0 7	5 7
63	3 00	38909 125	453986 332	0 085705	1	3 10	3 3			
41	37 5	529640 87	510050 58	1 038409	1	38 6	2 9	38 3	2 1	1 1
74	37 5	422527 632	412953 966	1 023183	1	38 0	1 3			
52	150	1935651 17	478139 936	4 048294	1	151	0 7	153	2 0	1 4
89	150	1998838 748	482256 923	4 144759	1	154	2 7			

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)
AAR - Concentration Found is Greater than 200 (Highest Standard)

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 5
Serum, Concentration of Cotinine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
04	N/A	1 / Day 1 - 0 0333h	1013120 233	465726 579	2 175354	1	81 0	21	05104620000241	AA97220-01 05104620000241 04 N/A Serum-1 1 / Day 1 - 0333h
04	N/A	1 / Day 1 - 0 0333h	1482549 434	494567 332	2 997670	1	112	22	05104620000257	AA97220-01 05104620000257 04 N/A Serum-1 1 / Day 1 - 0333h
04	N/A	1 / Day 1 - 0 0333h	2144401 419	482560 254	4 443800	1	165	20	05104620000273	AA97220-01 05104620000273 04 N/A Serum-1 1 / Day 1 - 0333h
04	N/A	1 / Day 1 - 0 0333h	2302626 039	517823 442	4 446740	1	166	23	05104620000289	AA97220-01 05104620000289 04 N/A Serum-1 1 / Day 1 - 0333h
04	N/A	2 / Day 1 0h	1097967 99	515861 421	2 128417	1	79 2	25	05104620000242	AA97220-01 05104620000242 04 N/A Serum-1 2 / Day 1 0h
04	N/A	2 / Day 1 0h	1300925 449	470112 418	2 767265	1	103	26	05104620000258	AA97220-01 05104620000258 04 N/A Serum-1 2 / Day 1 0h
04	N/A	2 / Day 1 0h	1886166 879	425952 028	4 428120	1	165	27	05104620000274	AA97220-01 05104620000274 04 N/A Serum-1 2 / Day 1 0h
04	N/A	2 / Day 1 0h	2259173 744	506084 608	4 464024	1	166	24	05104620000290	AA97220-01 05104620000290 04 N/A Serum-1 2 / Day 1 0h
04	N/A	3 / Day 1 0 05h	1089392 063	481678 357	2 261659	1	84 2	32	05104620000243	AA97220-01 05104620000243 04 N/A Serum-1 3 / Day 1 05h
04	N/A	3 / Day 1 0 05h	1649077 513	510807 42	3 228374	1	120	31	05104620000259	AA97220-01 05104620000259 04 N/A Serum-1 3 / Day 1 05h
04	N/A	3 / Day 1 0 05h	2087198 631	481446 042	4 335270	1	161	29	05104620000275	AA97220-01 05104620000275 04 N/A Serum-1 3 / Day 1 05h
04	N/A	3 / Day 1 0 05h	2418016 306	549550 453	4 399990	1	164	28	05104620000291	AA97220-01 05104620000291 04 N/A Serum-1 3 / Day 1 05h
04	N/A	4 / Day 1 0 0833h	1197746 367	535191 672	2 237976	1	83 3	35	05104620000244	AA97220-01 05104620000244 04 N/A Serum-1 4 / Day 1 0833h
04	N/A	4 / Day 1 0 0833h	1404116 235	520231 891	2 699020	1	100	33	05104620000260	AA97220-01 05104620000260 04 N/A Serum-1 4 / Day 1 0833h
04	N/A	4 / Day 1 0 0833h	2205805 426	536835 794	4 108902	1	153	34	05104620000276	AA97220-01 05104620000276 04 N/A Serum-1 4 / Day 1 0833h
04	N/A	4 / Day 1 0 0833h	2222087 995	498315 299	4 459201	1	166	36	05104620000292	AA97220-01 05104620000292 04 N/A Serum-1 4 / Day 1 0833h
04	N/A	5 / Day 1 0 125h	965454 601	454402 288	2 124669	1	79 1	40	05104620000245	AA97220-01 05104620000245 04 N/A Serum-1 5 / Day 1 125h
04	N/A	5 / Day 1 0 125h	1769753 624	608673 606	2 907558	1	108	39	05104620000261	AA97220-01 05104620000261 04 N/A Serum-1 5 / Day 1 125h
04	N/A	5 / Day 1 0 125h	1460162 141	338728 153	4 310720	1	161	38	05104620000277	AA97220-01 05104620000277 04 N/A Serum-1 5 / Day 1 125h
04	N/A	5 / Day 1 0 125h	2287232 906	551501 048	4 147287	1	154	37	05104620000293	AA97220-01 05104620000293 04 N/A Serum-1 5 / Day 1 125h
04	N/A	6 / Day 1 0 1667h	1244168 301	556346 584	2 236319	1	83 2	42	05104620000246	AA97220-01 05104620000246 04 N/A Serum-1 6 / Day 1 1667h
04	N/A	6 / Day 1 0 1667h	1578509 849	529122 23	2 983261	1	111	44	05104620000262	AA97220-01 05104620000262 04 N/A Serum-1 6 / Day 1 1667h
04	N/A	6 / Day 1 0 1667h	2067680 196	477741 742	4 328029	1	161	43	05104620000278	AA97220-01 05104620000278 04 N/A Serum-1 6 / Day 1 1667h
04	N/A	6 / Day 1 0 1667h	2319045 802	539908 692	4 295256	1	160	45	05104620000294	AA97220-01 05104620000294 04 N/A Serum-1 6 / Day 1 1667h
04	N/A	7 / Day 1 0 25h	1236259 485	545680 661	2 265537	1	84 3	46	05104620000247	AA97220-01 05104620000247 04 N/A Serum-1 7 / Day 1 25h
04	N/A	7 / Day 1 0 25h	1461563 628	514682 139	2 839740	1	106	47	05104620000263	AA97220-01 05104620000263 04 N/A Serum-1 7 / Day 1 25h
04	N/A	7 / Day 1 0 25h	2213331 077	522623 949	4 235036	1	158	49	05104620000279	AA97220-01 05104620000279 04 N/A Serum-1 7 / Day 1 25h
04	N/A	7 / Day 1 0 25h	2064429 526	487887 222	4 231366	1	158	48	05104620000295	AA97220-01 05104620000295 04 N/A Serum-1 7 / Day 1 25h
04	N/A	8 / Day 1 0 333h	952812 146	430481 359	2 213364	1	82 4	51	05104620000248	AA97220-01 05104620000248 04 N/A Serum-1 8 / Day 1 333h
04	N/A	8 / Day 1 0 333h	1408430 411	454831 478	3 096598	1	115	54	05104620000264	AA97220-01 05104620000264 04 N/A Serum-1 8 / Day 1 333h
04	N/A	8 / Day 1 0 333h	1884705 674	452653 852	4 163680	1	155	53	05104620000280	AA97220-01 05104620000280 04 N/A Serum-1 8 / Day 1 333h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
04	N/A	8 / Day 1 0 333h	2198603 491	486459 889	4 519599	1	168	50	05104620000296	AA97220-01 05104620000296 04 N/A Serum-1 8 / Day 1 333h
04	N/A	9 / Day 1 0 5h	1184908 196	526727 785	2 249565	1	83 7	56	05104620000249	AA97220-01 05104620000249 04 N/A Serum-1 9 / Day 1 5h
04	N/A	9 / Day 1 0 5h	1529303 866	521673 942	2 931532	1	109	55	05104620000265	AA97220-01 05104620000265 04 N/A Serum-1 9 / Day 1 5h
04	N/A	9 / Day 1 0 5h	2093305 663	498550 52	4 198783	1	156	57	05104620000281	AA97220-01 05104620000281 04 N/A Serum-1 9 / Day 1 5h
04	N/A	9 / Day 1 0 5h	2329497 087	519251 34	4 486261	1	167	58	05104620000297	AA97220-01 05104620000297 04 N/A Serum-1 9 / Day 1 5h
04	N/A	10 / Day 1 0 75h	1163496 421	486937 685	2 389415	1	88 9	59	05104620000250	AA97220-01 05104620000250 04 N/A Serum-1 10 / Day 1 75h
04	N/A	10 / Day 1 0 75h	1675815 776	561414 692	2 984987	1	111	60	05104620000266	AA97220-01 05104620000266 04 N/A Serum-1 10 / Day 1 75h
04	N/A	10 / Day 1 0 75h	2393521 376	577221 477	4 146626	1	154	62	05104620000282	AA97220-01 05104620000282 04 N/A Serum-1 10 / Day 1 75h
04	N/A	10 / Day 1 0 75h	2122685 178	445225 447	4 767664	1	178	61	05104620000298	AA97220-01 05104620000298 04 N/A Serum-1 10 / Day 1 75h
04	N/A	11 / Day 1 1h	1140188 266	502356 295	2 269680	1	84 5	64	05104620000251	AA97220-01 05104620000251 04 N/A Serum-1 11 / Day 1 1h
04	N/A	11 / Day 1 1h	1217004 62	421851 955	2 884909	1	107	67	05104620000267	AA97220-01 05104620000267 04 N/A Serum-1 11 / Day 1 1h
04	N/A	11 / Day 1 1h	1865071 69	451630 771	4 129638	1	154	65	05104620000283	AA97220-01 05104620000283 04 N/A Serum-1 11 / Day 1 1h
04	N/A	11 / Day 1 1h	1806906 669	387291 591	4 665494	1	174	66	05104620000299	AA97220-01 05104620000299 04 N/A Serum-1 11 / Day 1 1h
04	N/A	12 / Day 1 1 25h	930456 726	422562 094	2 201941	1	82 0	71	05104620000252	AA97220-01 05104620000252 04 N/A Serum-1 12 / Day 1 1 25h
04	N/A	12 / Day 1 1 25h	1273991 374	445981 419	2 856602	1	106	69	05104620000268	AA97220-01 05104620000268 04 N/A Serum-1 12 / Day 1 1 25h
04	N/A	12 / Day 1 1 25h	1728266 414	428637 181	4 032003	1	150	68	05104620000284	AA97220-01 05104620000284 04 N/A Serum-1 12 / Day 1 1 25h
04	N/A	12 / Day 1 1 25h	2219858 498	466098 551	4 762638	1	177	70	05104620000300	AA97220-01 05104620000300 04 N/A Serum-1 12 / Day 1 1 25h
04	N/A	13 / Day 1 1 5h	814459 822	363333 342	2 241632	1	83 4	73	05104620000253	AA97220-01 05104620000253 04 N/A Serum-1 13 / Day 1 1 5h
04	N/A	13 / Day 1 1 5h	1335816 611	469282 39	2 846509	1	106	72	05104620000269	AA97220-01 05104620000269 04 N/A Serum-1 13 / Day 1 1 5h
04	N/A	13 / Day 1 1 5h	1468329 588	356779 215	4 115513	1	153	75	05104620000285	AA97220-01 05104620000285 04 N/A Serum-1 13 / Day 1 1 5h
04	N/A	13 / Day 1 1 5h	1419876 593	326616 672	4 347226	1	162	76	05104620000301	AA97220-01 05104620000301 04 N/A Serum-1 13 / Day 1 1 5h
04	N/A	14 / Day 1 2h	910003 11	435172 972	2 091130	1	77 8	80	05104620000254	AA97220-01 05104620000254 04 N/A Serum-1 14 / Day 1 2h
04	N/A	14 / Day 1 2h	1217602 203	453197 324	2 686693	1	100	79	05104620000270	AA97220-01 05104620000270 04 N/A Serum-1 14 / Day 1 2h
04	N/A	14 / Day 1 2h	1687994 963	425978 01	3 962634	1	148	78	05104620000286	AA97220-01 05104620000286 04 N/A Serum-1 14 / Day 1 2h
04	N/A	14 / Day 1 2h	2001085 092	478724 577	4 180034	1	156	77	05104620000302	AA97220-01 05104620000302 04 N/A Serum-1 14 / Day 1 2h
04	N/A	15 / Day 1 2 5h	1207822 492	562961 326	2 145480	1	79 9	82	05104620000255	AA97220-01 05104620000255 04 N/A Serum-1 15 / Day 1 2 5h
04	N/A	15 / Day 1 2 5h	1362421 941	490589 335	2 777113	1	103	84	05104620000271	AA97220-01 05104620000271 04 N/A Serum-1 15 / Day 1 2 5h
04	N/A	15 / Day 1 2 5h	1844335 582	430013 632	4 289017	1	160	83	05104620000287	AA97220-01 05104620000287 04 N/A Serum-1 15 / Day 1 2 5h
04	N/A	15 / Day 1 2 5h	1879295 898	440172 959	4 269449	1	159	81	05104620000303	AA97220-01 05104620000303 04 N/A Serum-1 15 / Day 1 2 5h
04	N/A	16 / Day 1 3h	1039207 544	494816 177	2 100189	1	78 2	86	05104620000256	AA97220-01 05104620000256 04 N/A Serum-1 16 / Day 1 3h
04	N/A	16 / Day 1 3h	1304309 591	462179 784	2 822083	1	105	88	05104620000272	AA97220-01 05104620000272 04 N/A Serum-1 16 / Day 1 3h
04	N/A	16 / Day 1 3h	1875186 326	462294 49	4 056259	1	151	87	05104620000288	AA97220-01 05104620000288 04 N/A Serum-1 16 / Day 1 3h
04	N/A	16 / Day 1 3h	1779297 326	405609 393	4 386726	1	163	85	05104620000304	AA97220-01 05104620000304 04 N/A Serum-1 16 / Day 1 3h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1.00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 6
Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0.00		0	514215.917	0.000000	-0.0680		-0.0680	0.0
9	0.00		0	409099.714	0.000000	-0.0680			
10	1.00	1.00000	12407.923	433533.374	0.028620	0.966	-3.4		
11	2.00	0.250000	24821.447	410390.146	0.060483	2.12	6.0		
12	4.00	0.0625000	58493.587	497854.887	0.117491	4.18	4.5		
13	8.00	0.0156250	99757.71	461094.905	0.216350	7.75	-3.1		
14	16.0	0.00390625	205571.883	482074.095	0.426432	15.3	-4.4		
15	40.0	0.000625000	412411.9	377627.602	1.092113	39.4	-1.5		
16	80.0	0.000156250	791882.427	347802.585	2.276816	82.2	2.8		
17	160	0.0000390625	1613263.792	366586.199	4.400776	159	-0.6		
18	200	0.0000250000	1761596.607	318950.643	5.523101	200	0.0		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:

Slope = 0.0276749144

Intercept = 0.00188251753

R-Squared = 0.9983

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1.00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 6
 Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	2187208 264	410668 56	5 325970	1	192		194		0 7
2	0 00	2045556 504	380432 708	5 376921	1	194				
3	0 00	2302136 075	427322 018	5 387357	1	195				
4	0 00	2846483 865	527554 98	5 395616	1	195				
5	0 00	1977662 952	366944 402	5 389544	1	195				
91	0 00	2203704 16	415383 649	5 305226	1	192				
92	0 00	2386541 599	446220 766	5 348343	1	193				
30	3 00	35667 82	437448 803	0 081536	1	2 88	-4 0	2 88	-4 0	0 2
63	3 00	37020 612	455804 243	0 081220	1	2 87	-4 3			
41	37 5	411202 326	403626 551	1 018769	1	36 7	-2 1	36 3	-3 2	1 8
74	37 5	510622 03	514683 857	0 992108	1	35 8	-4 5			
52	150	1580841 133	397759 406	3 974365	1	144	-4 0	142	-5 3	2 0
89	150	1421866 633	366101 878	3 883800	1	140	-6 7			

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)
 AAR - Concentration Found is Greater than 200 (Highest Standard)

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 6
Serum, Concentration of Cotinine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
05	N/A	1 / Day 1 -0 0333h	2207066 071	412105 433	5 355586	1	193	20	05104620000337	AA97220-01 05104620000337 05 N/A Serum-1 1 / Day 1 - 0333h
05	N/A	1 / Day 1 -0 0333h	1813846 054	372171 252	4 873687	1	176	23	05104620000353	AA97220-01 05104620000353 05 N/A Serum-1 1 / Day 1 - 0333h
05	N/A	1 / Day 1 -0 0333h	2257950 948	377095 396	*5 987745	1	*AAR>(200)	22	05104620000369	AA97220-01 05104620000369 05 N/A Serum-1 1 / Day 1 - 0333h
05	N/A	1 / Day 1 -0 0333h	1877526 686	364104 597	5 156559	1	186	21	05104620000385	AA97220-01 05104620000385 05 N/A Serum-1 1 / Day 1 - 0333h
05	N/A	2 / Day 1 0h	2218793 353	425130 967	5 219082	1	189	27	05104620000338	AA97220-01 05104620000338 05 N/A Serum-1 2 / Day 1 0h
05	N/A	2 / Day 1 0h	1989526 043	406314 495	4 896518	1	177	26	05104620000354	AA97220-01 05104620000354 05 N/A Serum-1 2 / Day 1 0h
05	N/A	2 / Day 1 0h	2752024 778	468827 197	*5 870019	1	*AAR>(200)	24	05104620000370	AA97220-01 05104620000370 05 N/A Serum-1 2 / Day 1 0h
05	N/A	2 / Day 1 0h	1814803 622	361328 112	5 022592	1	181	25	05104620000386	AA97220-01 05104620000386 05 N/A Serum-1 2 / Day 1 0h
05	N/A	3 / Day 1 0 05h	1882522 403	379419 452	4 961586	1	179	28	05104620000339	AA97220-01 05104620000339 05 N/A Serum-1 3 / Day 1 05h
05	N/A	3 / Day 1 0 05h	1954287 372	411918 76	4 744351	1	171	32	05104620000355	AA97220-01 05104620000355 05 N/A Serum-1 3 / Day 1 05h
05	N/A	3 / Day 1 0 05h	2157551 573	358604 402	*6 016523	1	*AAR>(200)	29	05104620000371	AA97220-01 05104620000371 05 N/A Serum-1 3 / Day 1 05h
05	N/A	3 / Day 1 0 05h	1799337 877	337024 633	5 338891	1	193	31	05104620000387	AA97220-01 05104620000387 05 N/A Serum-1 3 / Day 1 05h
05	N/A	4 / Day 1 0 0833h	2038728 178	377259 141	5 404052	1	195	33	05104620000340	AA97220-01 05104620000340 05 N/A Serum-1 4 / Day 1 0833h
05	N/A	4 / Day 1 0 0833h	1778611 416	367235 008	4 843251	1	175	35	05104620000356	AA97220-01 05104620000356 05 N/A Serum-1 4 / Day 1 0833h
05	N/A	4 / Day 1 0 0833h	2741318 053	473177 667	*5 793422	1	*AAR>(200)	36	05104620000372	AA97220-01 05104620000372 05 N/A Serum-1 4 / Day 1 0833h
05	N/A	4 / Day 1 0 0833h	1924249 941	388840 605	4 948686	1	179	34	05104620000388	AA97220-01 05104620000388 05 N/A Serum-1 4 / Day 1 0833h
05	N/A	5 / Day 1 0 125h	2378159 756	461393 229	5 154301	1	186	38	05104620000341	AA97220-01 05104620000341 05 N/A Serum-1 5 / Day 1 125h
05	N/A	5 / Day 1 0 125h	1547678 021	348136 315	4 445609	1	161	37	05104620000357	AA97220-01 05104620000357 05 N/A Serum-1 5 / Day 1 125h
05	N/A	5 / Day 1 0 125h	2100252 968	352275 213	*5 961966	1	*AAR>(200)	39	05104620000373	AA97220-01 05104620000373 05 N/A Serum-1 5 / Day 1 125h
05	N/A	5 / Day 1 0 125h	2172735 777	436531 541	4 977271	1	180	40	05104620000389	AA97220-01 05104620000389 05 N/A Serum-1 5 / Day 1 125h
05	N/A	6 / Day 1 0 1667h	1978488 776	384801 258	5 141586	1	186	43	05104620000342	AA97220-01 05104620000342 05 N/A Serum-1 6 / Day 1 1667h
05	N/A	6 / Day 1 0 1667h	1650730 397	382334 722	4 317501	1	156	42	05104620000358	AA97220-01 05104620000358 05 N/A Serum-1 6 / Day 1 1667h
05	N/A	6 / Day 1 0 1667h	1940196 319	348256 584	*5 571169	1	*AAR>(200)	45	05104620000374	AA97220-01 05104620000374 05 N/A Serum-1 6 / Day 1 1667h
05	N/A	6 / Day 1 0 1667h	1889302 402	374421 16	5 045928	1	182	44	05104620000390	AA97220-01 05104620000390 05 N/A Serum-1 6 / Day 1 1667h
05	N/A	7 / Day 1 0 25h	1900281 253	381401 477	4 982365	1	180	48	05104620000343	AA97220-01 05104620000343 05 N/A Serum-1 7 / Day 1 25h
05	N/A	7 / Day 1 0 25h	1468416 544	323984 085	4 532372	1	164	47	05104620000359	AA97220-01 05104620000359 05 N/A Serum-1 7 / Day 1 25h
05	N/A	7 / Day 1 0 25h	2408964 675	405581 979	*5 939526	1	*AAR>(200)	49	05104620000375	AA97220-01 05104620000375 05 N/A Serum-1 7 / Day 1 25h
05	N/A	7 / Day 1 0 25h	1656610 043	341397 286	4 852441	1	175	46	05104620000391	AA97220-01 05104620000391 05 N/A Serum-1 7 / Day 1 25h
05	N/A	8 / Day 1 0 333h	1876095 373	369561 347	5 076547	1	183	51	05104620000344	AA97220-01 05104620000344 05 N/A Serum-1 8 / Day 1 333h
05	N/A	8 / Day 1 0 333h	1886601 514	375529 752	5 023840	1	181	50	05104620000360	AA97220-01 05104620000360 05 N/A Serum-1 8 / Day 1 333h
05	N/A	8 / Day 1 0 333h	2428456 38	415437 645	*5 845538	1	*AAR>(200)	53	05104620000376	AA97220-01 05104620000376 05 N/A Serum-1 8 / Day 1 333h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
05	N/A	8 / Day 1 0 333h	2111842 291	412350 192	5 121478	1	185	54	05104620000392	AA97220-01 05104620000392 05 N/A Serum-1 8 / Day 1 333h
05	N/A	9 / Day 1 0 5h	2000780 411	396621 601	5 044557	1	182	55	05104620000345	AA97220-01 05104620000345 05 N/A Serum-1 9 / Day 1 5h
05	N/A	9 / Day 1 0 5h	1934819 19	377718 457	5 122385	1	185	56	05104620000361	AA97220-01 05104620000361 05 N/A Serum-1 9 / Day 1 5h
05	N/A	9 / Day 1 0 5h	2973709 078	496260 772	*5 992231	1	*AAR>(200)	57	05104620000377	AA97220-01 05104620000377 05 N/A Serum-1 9 / Day 1 5h
05	N/A	9 / Day 1 0 5h	1997505 479	401251 396	4 978189	1	180	58	05104620000393	AA97220-01 05104620000393 05 N/A Serum-1 9 / Day 1 5h
05	N/A	10 / Day 1 0 75h	2025730 314	387311 431	5 230236	1	189	60	05104620000346	AA97220-01 05104620000346 05 N/A Serum-1 10 / Day 1 75h
05	N/A	10 / Day 1 0 75h	2038623 266	406044 748	5 020686	1	181	61	05104620000362	AA97220-01 05104620000362 05 N/A Serum-1 10 / Day 1 75h
05	N/A	10 / Day 1 0 75h	2057958 39	360857 002	*5 702975	1	*AAR>(200)	62	05104620000378	AA97220-01 05104620000378 05 N/A Serum-1 10 / Day 1 75h
05	N/A	10 / Day 1 0 75h	2056959 75	397526 415	5 174398	1	187	59	05104620000394	AA97220-01 05104620000394 05 N/A Serum-1 10 / Day 1 75h
05	N/A	11 / Day 1 1h	1766364 592	360895 313	4 894396	1	177	66	05104620000347	AA97220-01 05104620000347 05 N/A Serum-1 11 / Day 1 1h
05	N/A	11 / Day 1 1h	1992431 985	402494 634	4 950208	1	179	67	05104620000363	AA97220-01 05104620000363 05 N/A Serum-1 11 / Day 1 1h
05	N/A	11 / Day 1 1h	2359570 617	412543 411	*5 719569	1	*AAR>(200)	64	05104620000379	AA97220-01 05104620000379 05 N/A Serum-1 11 / Day 1 1h
05	N/A	11 / Day 1 1h	2096874 228	415675 729	5 044495	1	182	65	05104620000395	AA97220-01 05104620000395 05 N/A Serum-1 11 / Day 1 1h
05	N/A	12 / Day 1 1 25h	1759978 678	360729 835	4 878938	1	176	70	05104620000348	AA97220-01 05104620000348 05 N/A Serum-1 12 / Day 1 1 25h
05	N/A	12 / Day 1 1 25h	1904722 121	419620 463	4 539155	1	164	69	05104620000364	AA97220-01 05104620000364 05 N/A Serum-1 12 / Day 1 1 25h
05	N/A	12 / Day 1 1 25h	2443496 337	418283 685	*5 841720	1	*AAR>(200)	68	05104620000380	AA97220-01 05104620000380 05 N/A Serum-1 12 / Day 1 1 25h
05	N/A	12 / Day 1 1 25h	1784346 127	336201 035	5 307378	1	192	71	05104620000396	AA97220-01 05104620000396 05 N/A Serum-1 12 / Day 1 1 25h
05	N/A	13 / Day 1 1 5h	1714795 151	374076 612	4 584075	1	166	75	05104620000349	AA97220-01 05104620000349 05 N/A Serum-1 13 / Day 1 1 5h
05	N/A	13 / Day 1 1 5h	1952775 344	415009 378	4 705376	1	170	73	05104620000365	AA97220-01 05104620000365 05 N/A Serum-1 13 / Day 1 1 5h
05	N/A	13 / Day 1 1 5h	1938923 848	352979 399	5 493023	1	198	76	05104620000381	AA97220-01 05104620000381 05 N/A Serum-1 13 / Day 1 1 5h
05	N/A	13 / Day 1 1 5h	1783847 467	379739 792	4 697552	1	170	72	05104620000397	AA97220-01 05104620000397 05 N/A Serum-1 13 / Day 1 1 5h
05	N/A	14 / Day 1 2h	1993463 162	421551 398	4 728873	1	171	79	05104620000350	AA97220-01 05104620000350 05 N/A Serum-1 14 / Day 1 2h
05	N/A	14 / Day 1 2h	1919220 14	430767 368	4 455352	1	161	78	05104620000366	AA97220-01 05104620000366 05 N/A Serum-1 14 / Day 1 2h
05	N/A	14 / Day 1 2h	2189806 383	407928 722	5 368110	1	194	80	05104620000382	AA97220-01 05104620000382 05 N/A Serum-1 14 / Day 1 2h
05	N/A	14 / Day 1 2h	1979939 919	437330 265	4 527333	1	164	77	05104620000398	AA97220-01 05104620000398 05 N/A Serum-1 14 / Day 1 2h
05	N/A	15 / Day 1 2 5h	1842722 253	398784 637	4 620846	1	167	82	05104620000351	AA97220-01 05104620000351 05 N/A Serum-1 15 / Day 1 2 5h
05	N/A	15 / Day 1 2 5h	1850534 145	439209 126	4 213333	1	152	83	05104620000367	AA97220-01 05104620000367 05 N/A Serum-1 15 / Day 1 2 5h
05	N/A	15 / Day 1 2 5h	1918074 797	371116 887	5 168385	1	187	81	05104620000383	AA97220-01 05104620000383 05 N/A Serum-1 15 / Day 1 2 5h
05	N/A	15 / Day 1 2 5h	1976350 008	435709 841	4 535932	1	164	84	05104620000399	AA97220-01 05104620000399 05 N/A Serum-1 15 / Day 1 2 5h
05	N/A	16 / Day 1 3h	1806429 169	389737 683	4 634987	1	167	85	05104620000352	AA97220-01 05104620000352 05 N/A Serum-1 16 / Day 1 3h
05	N/A	16 / Day 1 3h	1793844 722	424335 771	4 227418	1	153	87	05104620000368	AA97220-01 05104620000368 05 N/A Serum-1 16 / Day 1 3h
05	N/A	16 / Day 1 3h	2183231 825	422580 472	5 166429	1	187	86	05104620000384	AA97220-01 05104620000384 05 N/A Serum-1 16 / Day 1 3h
05	N/A	16 / Day 1 3h	1753735 426	384393 223	4 562347	1	165	88	05104620000400	AA97220-01 05104620000400 05 N/A Serum-1 16 / Day 1 3h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1.00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

* - Sample Rejected

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 7
 Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		1996 812	1413583 092	0 001413	0 0784		0 0359	167 7
9	0 00		1701 237	2306891 727	0 000737	-0 00670			
10	1 00	1 00000	19970 725	2345474 287	0 008515	0 972	-2 8		
11	2 00	0 250000	40307 142	2284675 934	0 017642	2 12	6 0		
12	4 00	0 0625000	79252 383	2374601 576	0 033375	4 10	2 5		
13	8 00	0 0156250	128750 855	2122123 825	0 060671	7 53	-5 9		
14	16 0	0 00390625	307172 227	2418720 432	0 126998	15 9	-0 6		
15	40 0	0 000625000	712514 489	2323352 364	0 306675	38 5	-3 8		
16	80 0	0 000156250	1526447 886	2347049 318	0 650369	81 7	2 1		
17	160	0 0000390625	3092920 579	2440838 036	1 267155	159	-0 6		
18	200	0 0000250000	3403840 749	2080369 776	1 636171	206	3 0		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:

Slope = 0 00794761038

Intercept = 0 000790216638

R-Squared = 0 9981

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 7
 Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	3094974 147	1895988 348	1 632380	1	205		203		1 9
2	0 00	2937156 432	1813551 905	1 619560	1	204				
3	0 00	3026826 124	1856686 751	1 630230	1	205				
4	0 00	3185270 246	1961265 624	1 624089	1	204				
5	0 00	3025570 887	1821278 188	1 661235	1	209				
91	0 00	3196267 032	2040697 734	1 566262	1	197				
92	0 00	3536629 275	2223848 021	1 590320	1	200				
30	3 00	59779 063	2599813 563	0 022994	1	2 79	-7 0	2 83	-5 7	1 7
63	3 00	60666 1	2578065 435	0 023532	1	2 86	-4 7			
41	37 5	651859 753	2295321 64	0 283995	1	35 6	-5 1	35 4	-5 6	1 0
74	37 5	580024 535	2071057 692	0 280062	1	35 1	-6 4			
52	150	2584831 076	2203271 155	1 173179	1	148	-1 3	146	-2 7	2 4
89	150	2472657 658	2172480 33	1 138173	1	143	-4 7			

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)
 AAR - Concentration Found is Greater than 200 (Highest Standard)

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 7
Serum, Concentration of Cotinine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
05	N/A	1 / Day 1 - 0 0333h	3184607 322	2256342 73	1 411402	1	177	20	05104620000321	AA97220-01 05104620000321 05 N/A Serum-1 1 / Day 1 - 0333h
05	N/A	2 / Day 1 0h	3366245 89	2452535 294	1 372558	1	173	21	05104620000322	AA97220-01 05104620000322 05 N/A Serum-1 2 / Day 1 0h
05	N/A	3 / Day 1 0 05h	3309423 669	2375597 163	1 393091	1	175	22	05104620000323	AA97220-01 05104620000323 05 N/A Serum-1 3 / Day 1 05h
05	N/A	4 / Day 1 0 0833h	3394240 957	2472866 02	1 372594	1	173	23	05104620000324	AA97220-01 05104620000324 05 N/A Serum-1 4 / Day 1 0833h
05	N/A	5 / Day 1 0 125h	3437456 997	2600324 235	1 321934	1	166	24	05104620000325	AA97220-01 05104620000325 05 N/A Serum-1 5 / Day 1 125h
05	N/A	6 / Day 1 0 1667h	3051050 193	2240904 473	1 361526	1	171	25	05104620000326	AA97220-01 05104620000326 05 N/A Serum-1 6 / Day 1 1667h
05	N/A	7 / Day 1 0 25h	3146731 054	2259723 913	1 392529	1	175	26	05104620000327	AA97220-01 05104620000327 05 N/A Serum-1 7 / Day 1 25h
05	N/A	8 / Day 1 0 333h	3514915 56	2568114 212	1 368676	1	172	27	05104620000328	AA97220-01 05104620000328 05 N/A Serum-1 8 / Day 1 333h
05	N/A	9 / Day 1 0 5h	3424143 714	2469961 218	1 386315	1	174	28	05104620000329	AA97220-01 05104620000329 05 N/A Serum-1 9 / Day 1 5h
05	N/A	10 / Day 1 0 75h	3425832 513	2484382 63	1 378947	1	173	29	05104620000330	AA97220-01 05104620000330 05 N/A Serum-1 10 / Day 1 75h
05	N/A	11 / Day 1 1h	3382661 698	2365176 194	1 430194	1	180	31	05104620000331	AA97220-01 05104620000331 05 N/A Serum-1 11 / Day 1 1h
05	N/A	12 / Day 1 1 25h	3319247 581	2514680 517	1 319948	1	166	32	05104620000332	AA97220-01 05104620000332 05 N/A Serum-1 12 / Day 1 25h
05	N/A	13 / Day 1 1 5h	3396280 52	2538662 463	1 337823	1	168	33	05104620000333	AA97220-01 05104620000333 05 N/A Serum-1 13 / Day 1 1 5h
05	N/A	14 / Day 1 2h	3312076 666	2476047 233	1 337647	1	168	34	05104620000334	AA97220-01 05104620000334 05 N/A Serum-1 14 / Day 1 2h
05	N/A	15 / Day 1 2 5h	3334185 473	2550689 582	1 307170	1	164	35	05104620000335	AA97220-01 05104620000335 05 N/A Serum-1 15 / Day 1 2 5h
05	N/A	16 / Day 1 3h	3491005 87	2724373 088	1 281398	1	161	36	05104620000336	AA97220-01 05104620000336 05 N/A Serum-1 16 / Day 1 3h
06	N/A	1 / Day 1 - 0 0333h	1690648 451	2260776 672	0 747818	1	94 0	37	05104620000433	AA97220-01 05104620000433 06 N/A Serum-1 1 / Day 1 - 0333h
06	N/A	1 / Day 1 - 0 0333h	2295542 821	2264740 979	1 013601	1	127	38	05104620000449	AA97220-01 05104620000449 06 N/A Serum-1 1 / Day 1 - 0333h
06	N/A	1 / Day 1 - 0 0333h	2033783 68	2370557 766	0 857935	1	108	39	05104620000465	AA97220-01 05104620000465 06 N/A Serum-1 1 / Day 1 - 0333h
06	N/A	2 / Day 1 0h	1885930 156	2427755 134	0 776821	1	97 6	42	05104620000434	AA97220-01 05104620000434 06 N/A Serum-1 2 / Day 1 0h
06	N/A	2 / Day 1 0h	2437310 026	2367772 21	1 029368	1	129	40	05104620000450	AA97220-01 05104620000450 06 N/A Serum-1 2 / Day 1 0h
06	N/A	2 / Day 1 0h	2048832 707	2360722 96	0 867884	1	109	43	05104620000466	AA97220-01 05104620000466 06 N/A Serum-1 2 / Day 1 0h
06	N/A	3 / Day 1 0 05h	1857362 513	2496366 999	0 744026	1	93 5	44	05104620000435	AA97220-01 05104620000435 06 N/A Serum-1 3 / Day 1 05h
06	N/A	3 / Day 1 0 05h	2188989 377	2159553 367	1 013631	1	127	45	05104620000451	AA97220-01 05104620000451 06 N/A Serum-1 3 / Day 1 05h
06	N/A	3 / Day 1 0 05h	2044824 053	2380069 666	0 859145	1	108	46	05104620000467	AA97220-01 05104620000467 06 N/A Serum-1 3 / Day 1 05h
06	N/A	4 / Day 1 0 0833h	1706843 631	2298193 746	0 742689	1	93 3	47	05104620000436	AA97220-01 05104620000436 06 N/A Serum-1 4 / Day 1 0833h
06	N/A	4 / Day 1 0 0833h	2202458 789	2347227 806	0 938323	1	118	49	05104620000452	AA97220-01 05104620000452 06 N/A Serum-1 4 / Day 1 0833h
06	N/A	4 / Day 1 0 0833h	1997211 34	2316714 747	0 862088	1	108	48	05104620000468	AA97220-01 05104620000468 06 N/A Serum-1 4 / Day 1 0833h
06	N/A	5 / Day 1 0 125h	1622278 135	2149505 753	0 754721	1	94 9	50	05104620000437	AA97220-01 05104620000437 06 N/A Serum-1 5 / Day 1 125h
06	N/A	5 / Day 1 0 125h	2211551 056	2220724 103	0 995869	1	125	53	05104620000453	AA97220-01 05104620000453 06 N/A Serum-1 5 / Day 1 125h
06	N/A	5 / Day 1 0 125h	1524544 157	2001846 105	0 761569	1	95 7	51	05104620000469	AA97220-01 05104620000469 06 N/A Serum-1 5 / Day 1 125h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
06	N/A	6 / Day 1 0 1667h	2031641 235	2607709 954	0 779090	1	97 9	55	05104620000438	AA97220-01 05104620000438 06 N/A Serum-1 6 / Day 1 1667h
06	N/A	6 / Day 1 0 1667h	2445423 921	2424086 977	1 008802	1	127	54	05104620000454	AA97220-01 05104620000454 06 N/A Serum-1 6 / Day 1 1667h
06	N/A	6 / Day 1 0 1667h	2294256 21	2568738 895	0 893145	1	112	56	05104620000470	AA97220-01 05104620000470 06 N/A Serum-1 6 / Day 1 1667h
06	N/A	7 / Day 1 0 25h	1966095 444	2721007 198	0 722562	1	90 8	59	05104620000439	AA97220-01 05104620000439 06 N/A Serum-1 7 / Day 1 25h
06	N/A	7 / Day 1 0 25h	2562289 977	2603315 075	0 984241	1	124	57	05104620000455	AA97220-01 05104620000455 06 N/A Serum-1 7 / Day 1 25h
06	N/A	7 / Day 1 0 25h	2146447 246	2489509 997	0 862197	1	108	58	05104620000471	AA97220-01 05104620000471 06 N/A Serum-1 7 / Day 1 25h
06	N/A	8 / Day 1 0 333h	1760602 633	2499846 96	0 704284	1	88 5	61	05104620000440	AA97220-01 05104620000440 06 N/A Serum-1 8 / Day 1 333h
06	N/A	8 / Day 1 0 333h	2675299 452	2682724 015	0 997232	1	125	60	05104620000456	AA97220-01 05104620000456 06 N/A Serum-1 8 / Day 1 333h
06	N/A	8 / Day 1 0 333h	1843122 861	2116782 031	0 870719	1	109	62	05104620000472	AA97220-01 05104620000472 06 N/A Serum-1 8 / Day 1 333h
06	N/A	9 / Day 1 0 5h	1835987 965	2489192 437	0 737584	1	92 7	64	05104620000441	AA97220-01 05104620000441 06 N/A Serum-1 9 / Day 1 5h
06	N/A	9 / Day 1 0 5h	2668030 909	2738750 079	0 974178	1	122	66	05104620000457	AA97220-01 05104620000457 06 N/A Serum-1 9 / Day 1 5h
06	N/A	9 / Day 1 0 5h	2291694 915	2647146 946	0 865723	1	109	65	05104620000473	AA97220-01 05104620000473 06 N/A Serum-1 9 / Day 1 5h
06	N/A	10 / Day 1 0 75h	1835369 937	2467177 332	0 743915	1	93 5	69	05104620000442	AA97220-01 05104620000442 06 N/A Serum-1 10 / Day 1 75h
06	N/A	10 / Day 1 0 75h	2521659 641	2605020 807	0 968000	1	122	68	05104620000458	AA97220-01 05104620000458 06 N/A Serum-1 10 / Day 1 75h
06	N/A	10 / Day 1 0 75h	2275102 867	2557516 892	0 889575	1	112	67	05104620000474	AA97220-01 05104620000474 06 N/A Serum-1 10 / Day 1 75h
06	N/A	11 / Day 1 1h	1937338 655	2628587 435	0 737027	1	92 6	70	05104620000443	AA97220-01 05104620000443 06 N/A Serum-1 11 / Day 1 1h
06	N/A	11 / Day 1 1h	2498111 657	2699715 599	0 925324	1	116	72	05104620000459	AA97220-01 05104620000459 06 N/A Serum-1 11 / Day 1 1h
06	N/A	11 / Day 1 1h	2231024 231	2590729 455	0 861157	1	108	71	05104620000475	AA97220-01 05104620000475 06 N/A Serum-1 11 / Day 1 1h
06	N/A	12 / Day 1 1 25h	1459974 204	2008498 227	0 726898	1	91 4	73	05104620000444	AA97220-01 05104620000444 06 N/A Serum-1 12 / Day 1 1 25h
06	N/A	12 / Day 1 1 25h	2255063 495	2281912 631	0 988234	1	124	76	05104620000460	AA97220-01 05104620000460 06 N/A Serum-1 12 / Day 1 1 25h
06	N/A	12 / Day 1 1 25h	1823476 435	2104905 921	0 866298	1	109	75	05104620000476	AA97220-01 05104620000476 06 N/A Serum-1 12 / Day 1 1 25h
06	N/A	13 / Day 1 1 5h	1571888 052	2201977 528	0 713853	1	89 7	78	05104620000445	AA97220-01 05104620000445 06 N/A Serum-1 13 / Day 1 1 5h
06	N/A	13 / Day 1 1 5h	2311827 369	2464720 115	0 937968	1	118	79	05104620000461	AA97220-01 05104620000461 06 N/A Serum-1 13 / Day 1 1 5h
06	N/A	13 / Day 1 1 5h	2060982 684	2399130 632	0 859054	1	108	77	05104620000477	AA97220-01 05104620000477 06 N/A Serum-1 13 / Day 1 1 5h
06	N/A	14 / Day 1 2h	1450768 673	2079412 387	0 697682	1	87 7	81	05104620000446	AA97220-01 05104620000446 06 N/A Serum-1 14 / Day 1 2h
06	N/A	14 / Day 1 2h	2569539 468	2681247 603	0 958337	1	120	82	05104620000462	AA97220-01 05104620000462 06 N/A Serum-1 14 / Day 1 2h
06	N/A	14 / Day 1 2h	1845037 388	2310348 324	0 798597	1	100	80	05104620000478	AA97220-01 05104620000478 06 N/A Serum-1 14 / Day 1 2h
06	N/A	15 / Day 1 2 5h	1466213 709	2222787 255	0 659628	1	82 9	84	05104620000447	AA97220-01 05104620000447 06 N/A Serum-1 15 / Day 1 2 5h
06	N/A	15 / Day 1 2 5h	2134447 768	2171192 966	0 983076	1	124	83	05104620000463	AA97220-01 05104620000463 06 N/A Serum-1 15 / Day 1 2 5h
06	N/A	15 / Day 1 2 5h	1567267 314	2019567 768	0 776041	1	97 5	85	05104620000479	AA97220-01 05104620000479 06 N/A Serum-1 15 / Day 1 2 5h
06	N/A	16 / Day 1 3h	1533237 602	2311160 385	0 663406	1	83 4	88	05104620000448	AA97220-01 05104620000448 06 N/A Serum-1 16 / Day 1 3h
06	N/A	16 / Day 1 3h	1974653 562	2136912 32	0 924069	1	116	87	05104620000464	AA97220-01 05104620000464 06 N/A Serum-1 16 / Day 1 3h
06	N/A	16 / Day 1 3h	1571310 945	2053020 235	0 765366	1	96 2	86	05104620000480	AA97220-01 05104620000480 06 N/A Serum-1 16 / Day 1 3h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1.00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 8
Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		1515 693	2385307 907	0 000635	-0 107		-0 104	-4 1
9	0 00		1517 02	2219728 172	0 000683	-0 101			
10	1 00	1 00000	22081 265	2363046 998	0 009344	1 01	1 0		
11	2 00	0 250000	36723 62	2176413 477	0 016873	1 97	-1 5		
12	4 00	0 0625000	79707 198	2429951 842	0 032802	4 01	0 3		
13	8 00	0 0156250	155208 783	2451052 611	0 063323	7 92	-1 0		
14	16 0	0 00390625	292900 318	2324038 356	0 126031	15 9	-0 6		
15	40 0	0 000625000	815705 309	2637679 899	0 309251	39 4	-1 5		
16	80 0	0 000156250	1318093 269	2058980 426	0 640168	81 8	2 3		
17	160	0 0000390625	2961791 995	2342576 139	1 264331	162	1 3		
18	200	0 0000250000	3893141 015	2491810 149	1 562375	200	0 0		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:

Slope = 0 00781082820

Intercept = 0 00147170672

R-Squared = 0 9998

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 8
Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	3879281 632	2477205 805	1 565991	1	200		200		0 6
2	0 00	3834779 511	2423030 242	1 582638	1	202				
3	0 00	3637659 61	2322141 573	1 566511	1	200				
4	0 00	3781108 793	2418851 731	1 563183	1	200				
5	0 00	3415189 006	2205383 892	1 548569	1	198				
91	0 00	3994744 413	2555156 817	1 563405	1	200				
92	0 00	4156063	2666997 724	1 558330	1	199				
30	3 00	59742 733	2554387 899	0 023388	1	2 81	-6 3	3 44	14 7	25 9
63	3 00	51189 868	1540045 822	0 033239	1	4 07	35 7			
41	37 5	726067 583	2629495 329	0 276124	1	35 2	-6 1	35 4	-5 6	0 6
74	37 5	734258 291	2637063 828	0 278438	1	35 5	-5 3			
52	150	2476502 632	2261679 148	1 094984	1	140	-6 7	141	-6 0	0 5
89	150	2494176 943	2254366 416	1 106376	1	141	-6 0			

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)
AAR - Concentration Found is Greater than 200 (Highest Standard)

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 8
Serum, Concentration of Cotinine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
06	N/A	1 / Day 1 - 0 0333h	2155237 847	2535514 151	0 850020	1	109	21	05104620000401	AA97220-01 05104620000401 06 N/A Serum-1 1 / Day 1 - 0333h
06	N/A	1 / Day 1 - 0 0333h	1701236 705	2322468 381	0 732512	1	93 6	20	05104620000417	AA97220-01 05104620000417 06 N/A Serum-1 1 / Day 1 - 0333h
06	N/A	2 / Day 1 0h	2068739 739	2497363 31	0 828370	1	106	22	05104620000402	AA97220-01 05104620000402 06 N/A Serum-1 2 / Day 1 0h
06	N/A	2 / Day 1 0h	1611638 63	2169184 633	0 742970	1	94 9	23	05104620000418	AA97220-01 05104620000418 06 N/A Serum-1 2 / Day 1 0h
06	N/A	3 / Day 1 0 05h	1887573 573	2251891 029	0 838217	1	107	24	05104620000403	AA97220-01 05104620000403 06 N/A Serum-1 3 / Day 1 05h
06	N/A	3 / Day 1 0 05h	1843935 786	2478819 849	0 743876	1	95 0	25	05104620000419	AA97220-01 05104620000419 06 N/A Serum-1 3 / Day 1 05h
06	N/A	4 / Day 1 0 0833h	2284543 59	2638093 782	0 865983	1	111	27	05104620000404	AA97220-01 05104620000404 06 N/A Serum-1 4 / Day 1 0833h
06	N/A	4 / Day 1 0 0833h	1721525 18	2370668 459	0 726177	1	92 8	26	05104620000420	AA97220-01 05104620000420 06 N/A Serum-1 4 / Day 1 0833h
06	N/A	5 / Day 1 0 125h	2199262 711	2618691 748	0 839833	1	107	29	05104620000405	AA97220-01 05104620000405 06 N/A Serum-1 5 / Day 1 125h
06	N/A	5 / Day 1 0 125h	1823884 435	2544685 91	0 716742	1	91 6	28	05104620000421	AA97220-01 05104620000421 06 N/A Serum-1 5 / Day 1 125h
06	N/A	6 / Day 1 0 1667h	2039970 745	2477440 188	0 823419	1	105	32	05104620000406	AA97220-01 05104620000406 06 N/A Serum-1 6 / Day 1 1667h
06	N/A	6 / Day 1 0 1667h	1737918 455	2431380 917	0 714787	1	91 3	31	05104620000422	AA97220-01 05104620000422 06 N/A Serum-1 6 / Day 1 1667h
06	N/A	7 / Day 1 0 25h	1933373 609	2356434 181	0 820466	1	105	34	05104620000407	AA97220-01 05104620000407 06 N/A Serum-1 7 / Day 1 25h
06	N/A	7 / Day 1 0 25h	1741190 374	2416601 54	0 720512	1	92 1	33	05104620000423	AA97220-01 05104620000423 06 N/A Serum-1 7 / Day 1 25h
06	N/A	8 / Day 1 0 333h	1804905 352	2175710 597	0 829571	1	106	35	05104620000408	AA97220-01 05104620000408 06 N/A Serum-1 8 / Day 1 333h
06	N/A	8 / Day 1 0 333h	1887192 897	2708255 091	0 696830	1	89 0	36	05104620000424	AA97220-01 05104620000424 06 N/A Serum-1 8 / Day 1 333h
06	N/A	9 / Day 1 0 5h	2347098 399	2870400 623	0 817690	1	104	38	05104620000409	AA97220-01 05104620000409 06 N/A Serum-1 9 / Day 1 5h
06	N/A	9 / Day 1 0 5h	1765380 192	2505752 121	0 704531	1	90 0	37	05104620000425	AA97220-01 05104620000425 06 N/A Serum-1 9 / Day 1 5h
06	N/A	10 / Day 1 0 75h	2070264 871	2403166 858	0 861474	1	110	39	05104620000410	AA97220-01 05104620000410 06 N/A Serum-1 10 / Day 1 75h
06	N/A	10 / Day 1 0 75h	1863284 575	2641149 251	0 705482	1	90 1	40	05104620000426	AA97220-01 05104620000426 06 N/A Serum-1 10 / Day 1 75h
06	N/A	11 / Day 1 1h	2351457 966	2696666 735	0 871987	1	111	43	05104620000411	AA97220-01 05104620000411 06 N/A Serum-1 11 / Day 1 1h
06	N/A	11 / Day 1 1h	1797857 689	2451197 931	0 733461	1	93 7	42	05104620000427	AA97220-01 05104620000427 06 N/A Serum-1 11 / Day 1 1h
06	N/A	12 / Day 1 1 25h	1848518 909	2286217 072	0 808549	1	103	45	05104620000412	AA97220-01 05104620000412 06 N/A Serum-1 12 / Day 1 1 25h
06	N/A	12 / Day 1 1 25h	1931193 973	2619234 226	0 737312	1	94 2	44	05104620000428	AA97220-01 05104620000428 06 N/A Serum-1 12 / Day 1 1 25h
06	N/A	13 / Day 1 1 5h	2272992 204	2755377 683	0 824929	1	105	47	05104620000413	AA97220-01 05104620000413 06 N/A Serum-1 13 / Day 1 1 5h
06	N/A	13 / Day 1 1 5h	1743118 773	2335961 074	0 746211	1	95 3	46	05104620000429	AA97220-01 05104620000429 06 N/A Serum-1 13 / Day 1 1 5h
06	N/A	14 / Day 1 2h	1954173 426	2438029 782	0 801538	1	102	49	05104620000414	AA97220-01 05104620000414 06 N/A Serum-1 14 / Day 1 2h
06	N/A	14 / Day 1 2h	1684998 474	2372522 887	0 710214	1	90 7	48	05104620000430	AA97220-01 05104620000430 06 N/A Serum-1 14 / Day 1 2h
06	N/A	15 / Day 1 2 5h	1717031 721	2180828 424	0 787330	1	101	50	05104620000415	AA97220-01 05104620000415 06 N/A Serum-1 15 / Day 1 2 5h
06	N/A	15 / Day 1 2 5h	1587306 642	2278069 615	0 696777	1	89 0	51	05104620000431	AA97220-01 05104620000431 06 N/A Serum-1 15 / Day 1 2 5h
06	N/A	16 / Day 1 3h	1633361 353	2150353 926	0 759578	1	97 1	53	05104620000416	AA97220-01 05104620000416 06 N/A Serum-1 16 / Day 1 3h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
06	N/A	16 / Day 1 3h	1758324 169	2651042 271	0 663258	1	84 7	54	05104620000432	AA97220-01 05104620000432 06 N/A Serum-1 16 / Day 1 3h
07	N/A	1 / Day 1 - 0 0333h	1658017 01	2292110 345	0 723358	1	92 4	55	05104620000545	AA97220-01 05104620000545 07 N/A Serum-1 1 / Day 1 - 0333h
07	N/A	2 / Day 1 0h	1675871 989	2335147 986	0 717673	1	91 7	56	05104620000546	AA97220-01 05104620000546 07 N/A Serum-1 2 / Day 1 0h
07	N/A	3 / Day 1 0 05h	1680306 32	2395642 856	0 701401	1	89 6	57	05104620000547	AA97220-01 05104620000547 07 N/A Serum-1 3 / Day 1 05h
07	N/A	4 / Day 1 0 0833h	1670932 713	2350504 834	0 710882	1	90 8	58	05104620000548	AA97220-01 05104620000548 07 N/A Serum-1 4 / Day 1 0833h
07	N/A	5 / Day 1 0 125h	1684728 269	2301840 574	0 731905	1	93 5	59	05104620000549	AA97220-01 05104620000549 07 N/A Serum-1 5 / Day 1 125h
07	N/A	6 / Day 1 0 1667h	2188229 97	2919335 925	0 749564	1	95 8	60	05104620000550	AA97220-01 05104620000550 07 N/A Serum-1 6 / Day 1 1667h
07	N/A	7 / Day 1 0 25h	2143900 699	2789367 081	0 768598	1	98 2	61	05104620000551	AA97220-01 05104620000551 07 N/A Serum-1 7 / Day 1 25h
07	N/A	8 / Day 1 0 333h	1637414 8	2298949 371	0 712245	1	91 0	62	05104620000552	AA97220-01 05104620000552 07 N/A Serum-1 8 / Day 1 333h
07	N/A	9 / Day 1 0 5h	1834098 747	2363822 153	0 775904	1	99 1	64	05104620000553	AA97220-01 05104620000553 07 N/A Serum-1 9 / Day 1 5h
07	N/A	10 / Day 1 0 75h	1877321 289	2308448 403	0 813239	1	104	65	05104620000554	AA97220-01 05104620000554 07 N/A Serum-1 10 / Day 1 75h
07	N/A	11 / Day 1 1h	2177805 982	2764322 07	0 787826	1	101	66	05104620000555	AA97220-01 05104620000555 07 N/A Serum-1 11 / Day 1 1h
07	N/A	12 / Day 1 1 25h	2042299 349	2601084 517	0 785172	1	100	67	05104620000556	AA97220-01 05104620000556 07 N/A Serum-1 12 / Day 1 1 25h
07	N/A	13 / Day 1 1 5h	2127061 877	2642711 448	0 804879	1	103	68	05104620000557	AA97220-01 05104620000557 07 N/A Serum-1 13 / Day 1 1 5h
07	N/A	14 / Day 1 2h	2095413 161	2842381 852	0 737203	1	94 2	69	05104620000558	AA97220-01 05104620000558 07 N/A Serum-1 14 / Day 1 2h
07	N/A	15 / Day 1 2 5h	1801700 483	2609160 898	0 690529	1	88 2	70	05104620000559	AA97220-01 05104620000559 07 N/A Serum-1 15 / Day 1 2 5h
07	N/A	16 / Day 1 3h	1624321 865	2440732 578	0 665506	1	85 0	71	05104620000560	AA97220-01 05104620000560 07 N/A Serum-1 16 / Day 1 3h
08	N/A	1 / Day 1 - 0 0333h	3335551 265	2565145 43	1 300336	1	166	72	05104620000625	AA97220-01 05104620000625 08 N/A Serum-1 1 / Day 1 - 0333h
08	N/A	2 / Day 1 0h	3632587 723	2747605 273	1 322092	1	169	73	05104620000626	AA97220-01 05104620000626 08 N/A Serum-1 2 / Day 1 0h
08	N/A	3 / Day 1 0 05h	3907866 236	2990485 49	1 306766	1	167	75	05104620000627	AA97220-01 05104620000627 08 N/A Serum-1 3 / Day 1 05h
08	N/A	4 / Day 1 0 0833h	3338614 055	2565328 564	1 301437	1	166	76	05104620000628	AA97220-01 05104620000628 08 N/A Serum-1 4 / Day 1 0833h
08	N/A	5 / Day 1 0 125h	3307393 227	2565096 388	1 289384	1	165	77	05104620000629	AA97220-01 05104620000629 08 N/A Serum-1 5 / Day 1 125h
08	N/A	6 / Day 1 0 1667h	4192218 894	3302420 956	1 269438	1	162	78	05104620000630	AA97220-01 05104620000630 08 N/A Serum-1 6 / Day 1 1667h
08	N/A	7 / Day 1 0 25h	3374727 159	2617416 055	1 289335	1	165	79	05104620000631	AA97220-01 05104620000631 08 N/A Serum-1 7 / Day 1 25h
08	N/A	8 / Day 1 0 333h	3985596 712	3056012 31	1 304182	1	167	80	05104620000632	AA97220-01 05104620000632 08 N/A Serum-1 8 / Day 1 333h
08	N/A	9 / Day 1 0 5h	3615537 011	2770148 406	1 305178	1	167	81	05104620000633	AA97220-01 05104620000633 08 N/A Serum-1 9 / Day 1 5h
08	N/A	10 / Day 1 0 75h	3506886 416	2690272 355	1 303543	1	167	82	05104620000634	AA97220-01 05104620000634 08 N/A Serum-1 10 / Day 1 75h
08	N/A	11 / Day 1 1h	4205342 985	3227195 888	1 303095	1	167	83	05104620000635	AA97220-01 05104620000635 08 N/A Serum-1 11 / Day 1 1h
08	N/A	12 / Day 1 1 25h	3263670 584	2505401 14	1 302654	1	167	84	05104620000636	AA97220-01 05104620000636 08 N/A Serum-1 12 / Day 1 1 25h
08	N/A	13 / Day 1 1 5h	3582139 757	2682995 925	1 335127	1	171	85	05104620000637	AA97220-01 05104620000637 08 N/A Serum-1 13 / Day 1 1 5h
08	N/A	14 / Day 1 2h	3384212 334	2533154 911	1 335967	1	171	86	05104620000638	AA97220-01 05104620000638 08 N/A Serum-1 14 / Day 1 2h
08	N/A	15 / Day 1 2 5h	3461676 817	2747546 345	1 259916	1	161	87	05104620000639	AA97220-01 05104620000639 08 N/A Serum-1 15 / Day 1 2 5h
08	N/A	16 / Day 1 3h	2190821 221	1736069 28	1 261943	1	161	88	05104620000640	AA97220-01 05104620000640 08 N/A Serum-1 16 / Day 1 3h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1.00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 12
Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		2678 078	2188689 702	0 001224	0 0000267		-0 0271	-141 7
9	0 00		1670 299	2072855 855	0 000806	-0 0543			
10	1 00	1 00000	18808 73	2133347 137	0 008817	0 988	-1 2		
11	2 00	0 250000	40654 747	2427480 875	0 016748	2 02	1 0		
12	4 00	0 0625000	80792 563	2421386 531	0 033366	4 18	4 5		
13	8 00	0 0156250	144486 627	2325349 034	0 062135	7 92	-1 0		
14	16 0	0 00390625	269282 165	2237536 36	0 120348	15 5	-3 1		
15	40 0	0 000625000	657177 443	2167285 393	0 303226	39 3	-1 8		
16	80 0	0 000156250	1348489 4	2188281 114	0 616232	80 0	0 0		
17	160	0 0000390625	2736306 17	2187953 424	1 250624	162	1 3		
18	200	0 0000250000	3357769 125	2177205 627	1 542238	200	0 0		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:

Slope = 0 00768905581

Intercept = 0 00122379494

R-Squared = 0 9993

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 12
 Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	3523822 742	2254619 321	1 562935	1	203		199		1 3
2	0 00	3447154 095	2230540 047	1 545435	1	201				
3	0 00	3340667 544	2187717 062	1 527011	1	198				
4	0 00	3348758 719	2176576 37	1 538544	1	200				
5	0 00	3581013 43	2342055 758	1 529004	1	199				
91	0 00	3528522 394	2352012 799	1 500214	1	195				
92	0 00	3506871 78	2305179 133	1 521301	1	198				
30	3 00	58043 028	2505659 983	0 023165	1	2 85	-5 0	2 84	-5 3	0 5
63	3 00	76006 383	3306890 175	0 022984	1	2 83	-5 7			
41	37 5	681480 216	2411091 609	0 282644	1	36 6	-2 4	36 3	-3 2	1 2
74	37 5	794315 682	2854338 564	0 278284	1	36 0	-4 0			
52	150	2684102 914	2468851 657	1 087187	1	141	-6 0	144	-4 0	2 9
89	150	2841063 181	2515672 524	1 129345	1	147	-2 0			

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)
 AAR - Concentration Found is Greater than 200 (Highest Standard)

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 12
Serum, Concentration of Cotinine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
10	N/A	1 / Day 1 -0 0333h	5311264 683	2245550 545	*2 365239	1	*AAR>(200)	20	05104620000721	AA97220-01 05104620000721 10 N/A Serum-1 1 / Day 1 - 0333h
10	N/A	1 / Day 1 -0 0333h	4681692 598	2389965 548	*1 958895	1	*AAR>(200)	21	05104620000737	AA97220-01 05104620000737 10 N/A Serum-1 1 / Day 1 - 0333h
10	N/A	2 / Day 1 0h	5604884 538	2393791 54	*2 341425	1	*AAR>(200)	22	05104620000722	AA97220-01 05104620000722 10 N/A Serum-1 2 / Day 1 0h
10	N/A	2 / Day 1 0h	4667856 15	2399806 999	*1 945096	1	*AAR>(200)	23	05104620000738	AA97220-01 05104620000738 10 N/A Serum-1 2 / Day 1 0h
10	N/A	3 / Day 1 0 05h	5363158 607	2238454 523	*2 395920	1	*AAR>(200)	25	05104620000723	AA97220-01 05104620000723 10 N/A Serum-1 3 / Day 1 05h
10	N/A	3 / Day 1 0 05h	4701338 097	2380941 398	*1 974571	1	*AAR>(200)	24	05104620000739	AA97220-01 05104620000739 10 N/A Serum-1 3 / Day 1 05h
10	N/A	4 / Day 1 0 0833h	5383381 595	2286442 777	*2 354479	1	*AAR>(200)	27	05104620000724	AA97220-01 05104620000724 10 N/A Serum-1 4 / Day 1 0833h
10	N/A	4 / Day 1 0 0833h	4517510 992	2352425 388	*1 920363	1	*AAR>(200)	26	05104620000740	AA97220-01 05104620000740 10 N/A Serum-1 4 / Day 1 0833h
10	N/A	5 / Day 1 0 125h	5600585 058	2383605 338	*2 349628	1	*AAR>(200)	28	05104620000725	AA97220-01 05104620000725 10 N/A Serum-1 5 / Day 1 125h
10	N/A	5 / Day 1 0 125h	4688397 576	2427110 461	*1 931679	1	*AAR>(200)	29	05104620000741	AA97220-01 05104620000741 10 N/A Serum-1 5 / Day 1 125h
10	N/A	6 / Day 1 0 1667h	5811720 103	2457495 577	*2 364895	1	*AAR>(200)	32	05104620000726	AA97220-01 05104620000726 10 N/A Serum-1 6 / Day 1 1667h
10	N/A	6 / Day 1 0 1667h	4773204 624	2404568 847	*1 985056	1	*AAR>(200)	31	05104620000742	AA97220-01 05104620000742 10 N/A Serum-1 6 / Day 1 1667h
10	N/A	7 / Day 1 0 25h	5875992 666	2505419 491	*2 345313	1	*AAR>(200)	33	05104620000727	AA97220-01 05104620000727 10 N/A Serum-1 7 / Day 1 25h
10	N/A	7 / Day 1 0 25h	4850150 265	2440554 883	*1 987315	1	*AAR>(200)	34	05104620000743	AA97220-01 05104620000743 10 N/A Serum-1 7 / Day 1 25h
10	N/A	8 / Day 1 0 333h	5736504 308	2421389 892	*2 369096	1	*AAR>(200)	35	05104620000728	AA97220-01 05104620000728 10 N/A Serum-1 8 / Day 1 333h
10	N/A	8 / Day 1 0 333h	5189292 909	2440680 165	*2 126167	1	*AAR>(200)	36	05104620000744	AA97220-01 05104620000744 10 N/A Serum-1 8 / Day 1 333h
10	N/A	9 / Day 1 0 5h	5894471 2	2485490 575	*2 371552	1	*AAR>(200)	38	05104620000729	AA97220-01 05104620000729 10 N/A Serum-1 9 / Day 1 5h
10	N/A	9 / Day 1 0 5h	4728919 162	2418971 829	*1 954929	1	*AAR>(200)	37	05104620000745	AA97220-01 05104620000745 10 N/A Serum-1 9 / Day 1 5h
10	N/A	10 / Day 1 0 75h	5659246 302	2394150 594	*2 363780	1	*AAR>(200)	40	05104620000730	AA97220-01 05104620000730 10 N/A Serum-1 10 / Day 1 75h
10	N/A	10 / Day 1 0 75h	4774939 517	2505695 675	*1 905634	1	*AAR>(200)	39	05104620000746	AA97220-01 05104620000746 10 N/A Serum-1 10 / Day 1 75h
10	N/A	11 / Day 1 1h	5611233 096	2429941 079	*2 309205	1	*AAR>(200)	42	05104620000731	AA97220-01 05104620000731 10 N/A Serum-1 11 / Day 1 1h
10	N/A	11 / Day 1 1h	4744776 095	2402646 985	*1 974812	1	*AAR>(200)	43	05104620000747	AA97220-01 05104620000747 10 N/A Serum-1 11 / Day 1 1h
10	N/A	12 / Day 1 1 25h	5555616 757	2404196 446	*2 310800	1	*AAR>(200)	44	05104620000732	AA97220-01 05104620000732 10 N/A Serum-1 12 / Day 1 1 25h
10	N/A	12 / Day 1 1 25h	4659734 512	2370833 765	*1 965441	1	*AAR>(200)	45	05104620000748	AA97220-01 05104620000748 10 N/A Serum-1 12 / Day 1 1 25h
10	N/A	13 / Day 1 1 5h	5627823 718	2333633 023	*2 411615	1	*AAR>(200)	47	05104620000733	AA97220-01 05104620000733 10 N/A Serum-1 13 / Day 1 1 5h
10	N/A	13 / Day 1 1 5h	4701957 563	2400706 082	*1 958573	1	*AAR>(200)	46	05104620000749	AA97220-01 05104620000749 10 N/A Serum-1 13 / Day 1 1 5h
10	N/A	14 / Day 1 2h	5301191 659	2247979 086	*2 358203	1	*AAR>(200)	49	05104620000734	AA97220-01 05104620000734 10 N/A Serum-1 14 / Day 1 2h
10	N/A	14 / Day 1 2h	4515572 982	2351204 684	*1 920536	1	*AAR>(200)	48	05104620000750	AA97220-01 05104620000750 10 N/A Serum-1 14 / Day 1 2h
10	N/A	15 / Day 1 2 5h	5386242 579	2478731 054	*2 172984	1	*AAR>(200)	51	05104620000735	AA97220-01 05104620000735 10 N/A Serum-1 15 / Day 1 2 5h
10	N/A	15 / Day 1 2 5h	4497175 321	2354812 917	*1 909780	1	*AAR>(200)	50	05104620000751	AA97220-01 05104620000751 10 N/A Serum-1 15 / Day 1 2 5h
10	N/A	16 / Day 1 3h	4990079 58	2318228 464	*2 152540	1	*AAR>(200)	53	05104620000736	AA97220-01 05104620000736 10 N/A Serum-1 16 / Day 1 3h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
10	N/A	16 / Day 1 3h	4301045 687	2331445 7	*1 844798	1	*AAR>(200)	54	05104620000752	AA97220-01 05104620000752 10 N/A Serum-1 16 / Day 1 3h
11	N/A	1 / Day 1 -0 0333h	3142509 182	2399275 506	1 309774	1	170	55	05104620000849	AA97220-01 05104620000849 11 N/A Serum-1 1 / Day 1 - 0333h
11	N/A	1 / Day 1 -0 0333h	4507573 751	2313646 233	*1 948255	1	*AAR>(200)	56	05104620000865	AA97220-01 05104620000865 11 N/A Serum-1 1 / Day 1 - 0333h
11	N/A	2 / Day 1 0h	2710465 297	2336132 855	1 160236	1	151	58	05104620000850	AA97220-01 05104620000850 11 N/A Serum-1 2 / Day 1 0h
11	N/A	2 / Day 1 0h	4778168	2190259 461	*2 181553	1	*AAR>(200)	57	05104620000866	AA97220-01 05104620000866 11 N/A Serum-1 2 / Day 1 0h
11	N/A	3 / Day 1 0 05h	2694301 65	2324162 824	1 159257	1	151	59	05104620000851	AA97220-01 05104620000851 11 N/A Serum-1 3 / Day 1 05h
11	N/A	3 / Day 1 0 05h	4899586 977	2703874 826	*1 812061	1	*AAR>(200)	60	05104620000867	AA97220-01 05104620000867 11 N/A Serum-1 3 / Day 1 05h
11	N/A	4 / Day 1 0 0833h	3536481 903	3111699 268	1 136511	1	148	62	05104620000852	AA97220-01 05104620000852 11 N/A Serum-1 4 / Day 1 0833h
11	N/A	4 / Day 1 0 0833h	5088530 707	2617988 384	*1 943680	1	*AAR>(200)	61	05104620000868	AA97220-01 05104620000868 11 N/A Serum-1 4 / Day 1 0833h
11	N/A	5 / Day 1 0 125h	3384882 22	2969408 739	1 139918	1	148	65	05104620000853	AA97220-01 05104620000853 11 N/A Serum-1 5 / Day 1 125h
11	N/A	5 / Day 1 0 125h	6122311 524	3357529 093	*1 823457	1	*AAR>(200)	64	05104620000869	AA97220-01 05104620000869 11 N/A Serum-1 5 / Day 1 125h
11	N/A	6 / Day 1 0 1667h	2922184 531	2445629 416	1 194860	1	155	67	05104620000854	AA97220-01 05104620000854 11 N/A Serum-1 6 / Day 1 1667h
11	N/A	6 / Day 1 0 1667h	4736890 697	2528087 326	*1 873705	1	*AAR>(200)	66	05104620000870	AA97220-01 05104620000870 11 N/A Serum-1 6 / Day 1 1667h
11	N/A	7 / Day 1 0 25h	2989517 199	2517374 707	1 187554	1	154	68	05104620000855	AA97220-01 05104620000855 11 N/A Serum-1 7 / Day 1 25h
11	N/A	7 / Day 1 0 25h	4736973 321	2491866 548	*1 900974	1	*AAR>(200)	69	05104620000871	AA97220-01 05104620000871 11 N/A Serum-1 7 / Day 1 25h
11	N/A	8 / Day 1 0 333h	2845018 067	2403719 864	1 183590	1	154	71	05104620000856	AA97220-01 05104620000856 11 N/A Serum-1 8 / Day 1 333h
11	N/A	8 / Day 1 0 333h	4581588 156	2421813 371	*1 891801	1	*AAR>(200)	70	05104620000872	AA97220-01 05104620000872 11 N/A Serum-1 8 / Day 1 333h
11	N/A	9 / Day 1 0 5h	3340517 785	2648365 464	1 261351	1	164	73	05104620000857	AA97220-01 05104620000857 11 N/A Serum-1 9 / Day 1 5h
11	N/A	9 / Day 1 0 5h	5367901 344	2835589 107	*1 893046	1	*AAR>(200)	72	05104620000873	AA97220-01 05104620000873 11 N/A Serum-1 9 / Day 1 5h
11	N/A	10 / Day 1 0 75h	3128659 112	2750039 106	1 137678	1	148	76	05104620000858	AA97220-01 05104620000858 11 N/A Serum-1 10 / Day 1 75h
11	N/A	10 / Day 1 0 75h	4877543 07	2623268 928	*1 859338	1	*AAR>(200)	75	05104620000874	AA97220-01 05104620000874 11 N/A Serum-1 10 / Day 1 75h
11	N/A	11 / Day 1 1h	3285686 956	2787405 858	1 178762	1	153	77	05104620000859	AA97220-01 05104620000859 11 N/A Serum-1 11 / Day 1 1h
11	N/A	11 / Day 1 1h	4749861 663	2570808 46	*1 847614	1	*AAR>(200)	78	05104620000875	AA97220-01 05104620000875 11 N/A Serum-1 11 / Day 1 1h
11	N/A	12 / Day 1 1 25h	3326766 713	2828290 197	1 176247	1	153	79	05104620000860	AA97220-01 05104620000860 11 N/A Serum-1 12 / Day 1 1 25h
11	N/A	12 / Day 1 1 25h	5715054 744	2849246 567	*2 005813	1	*AAR>(200)	80	05104620000876	AA97220-01 05104620000876 11 N/A Serum-1 12 / Day 1 1 25h
11	N/A	13 / Day 1 1 5h	3768039 563	2802032 687	1 344752	1	175	81	05104620000861	AA97220-01 05104620000861 11 N/A Serum-1 13 / Day 1 1 5h
11	N/A	13 / Day 1 1 5h	5208627 321	2816818 703	*1 849117	1	*AAR>(200)	82	05104620000877	AA97220-01 05104620000877 11 N/A Serum-1 13 / Day 1 1 5h
11	N/A	14 / Day 1 2h	3289237 578	2806086 213	1 172180	1	152	84	05104620000862	AA97220-01 05104620000862 11 N/A Serum-1 14 / Day 1 2h
11	N/A	14 / Day 1 2h	6090338 126	2928009 994	*2 080026	1	*AAR>(200)	83	05104620000878	AA97220-01 05104620000878 11 N/A Serum-1 14 / Day 1 2h
11	N/A	15 / Day 1 2 5h	3126603 747	2747419 052	1 138015	1	148	86	05104620000863	AA97220-01 05104620000863 11 N/A Serum-1 15 / Day 1 2 5h
11	N/A	15 / Day 1 2 5h	4938727 122	2895324 052	*1 705760	1	*AAR>(200)	85	05104620000879	AA97220-01 05104620000879 11 N/A Serum-1 15 / Day 1 2 5h
11	N/A	16 / Day 1 3h	2865755 87	2569917 703	1 115116	1	145	87	05104620000864	AA97220-01 05104620000864 11 N/A Serum-1 16 / Day 1 3h
11	N/A	16 / Day 1 3h	5438234 955	3027332 57	*1 796378	1	*AAR>(200)	88	05104620000880	AA97220-01 05104620000880 11 N/A Serum-1 16 / Day 1 3h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1.00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

* - Sample Rejected

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 13
 Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		7994 785	3961159 083	0 002018	-0 0116		-0 0302	-87 1
9	0 00		7549 972	4339028 351	0 001740	-0 0488			
10	1 00	1 00000	41677 89	4449231 556	0 009367	0 972	-2 8		
11	2 00	0 250000	69274 058	3871998 692	0 017891	2 11	5 5		
12	4 00	0 0625000	139870 628	4338019 279	0 032243	4 03	0 8		
13	8 00	0 0156250	261846 892	4281923 338	0 061152	7 90	-1 3		
14	16 0	0 00390625	541825 24	4427668 391	0 122373	16 1	0 6		
15	40 0	0 000625000	1156419 465	3967092 692	0 291503	38 7	-3 3		
16	80 0	0 000156250	2451865 285	3986202 002	0 615088	82 0	2 5		
17	160	0 0000390625	5050941 054	4296896 102	1 175486	157	-1 9		
18	200	0 0000250000	7160650 546	4801744 82	1 491260	199	-0 5		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:

Slope = 0 00747387357

Intercept = 0 00210444953

R-Squared = 0 9990

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 13
Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	5810649 159	3952568 626	1 470094	1	196		197		0 5
2	0 00	5759977 94	3926325 417	1 467015	1	196				
3	0 00	5789927 712	3913114 864	1 479621	1	198				
4	0 00	6518824 764	4393954 316	1 483590	1	198				
5	0 00	5948729 288	4063542 122	1 463927	1	196				
91	0 00	8722102 614	5918322 431	1 473746	1	197				
92	0 00	8748951 287	5929350 323	1 475533	1	197				
30	3 00	102802 048	4444822 424	0 023128	1	2 81	-6 3	2 73	-9 0	4 1
63	3 00	104474 115	4767664 058	0 021913	1	2 65	-11 7			
41	37 5	1099574 982	4070629 097	0 270124	1	35 9	-4 3	36 5	-2 7	2 1
74	37 5	1194050 29	4288551 394	0 278427	1	37 0	-1 3			
52	150	4735011 784	4264638 831	1 110296	1	148	-1 3	144	-4 0	4 4
89	150	5468378 933	5236381 629	1 044305	1	139	-7 3			

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)
AAR - Concentration Found is Greater than 200 (Highest Standard)

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 13
Serum, Concentration of Cotinine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
11	N/A	1 / Day 1 -0 0333h	5937838 704	4172619 591	1 423048	1	190	20	05104620000801	AA97220-01 05104620000801 11 N/A Serum-1 1 / Day 1 - 0333h
11	N/A	1 / Day 1 -0 0333h	7417615 043	4326618 558	*1 714414	1	*AAR>(200)	21	05104620000817	AA97220-01 05104620000817 11 N/A Serum-1 1 / Day 1 - 0333h
11	N/A	1 / Day 1 -0 0333h	5888956 609	4274580 548	1 377669	1	184	22	05104620000833	AA97220-01 05104620000833 11 N/A Serum-1 1 / Day 1 - 0333h
11	N/A	2 / Day 1 0h	5662583 676	4060213 299	1 394652	1	186	25	05104620000802	AA97220-01 05104620000802 11 N/A Serum-1 2 / Day 1 0h
11	N/A	2 / Day 1 0h	6852163 159	4071658 764	*1 682892	1	*AAR>(200)	23	05104620000818	AA97220-01 05104620000818 11 N/A Serum-1 2 / Day 1 0h
11	N/A	2 / Day 1 0h	5482502 845	4013496 684	1 366017	1	182	24	05104620000834	AA97220-01 05104620000834 11 N/A Serum-1 2 / Day 1 0h
11	N/A	3 / Day 1 0 05h	6570678 454	4614639 231	1 423877	1	190	28	05104620000803	AA97220-01 05104620000803 11 N/A Serum-1 3 / Day 1 05h
11	N/A	3 / Day 1 0 05h	7652388 312	4502377 42	*1 699633	1	*AAR>(200)	27	05104620000819	AA97220-01 05104620000819 11 N/A Serum-1 3 / Day 1 05h
11	N/A	3 / Day 1 0 05h	5767826 569	4211634 651	1 369498	1	183	26	05104620000835	AA97220-01 05104620000835 11 N/A Serum-1 3 / Day 1 05h
11	N/A	4 / Day 1 0 0833h	5699918 023	3972703 51	1 434771	1	192	32	05104620000804	AA97220-01 05104620000804 11 N/A Serum-1 4 / Day 1 0833h
11	N/A	4 / Day 1 0 0833h	6834902 992	4023335 628	*1 698815	1	*AAR>(200)	31	05104620000820	AA97220-01 05104620000820 11 N/A Serum-1 4 / Day 1 0833h
11	N/A	4 / Day 1 0 0833h	6147984 383	4431233 384	1 387421	1	185	29	05104620000836	AA97220-01 05104620000836 11 N/A Serum-1 4 / Day 1 0833h
11	N/A	5 / Day 1 0 125h	5936436 818	4192906 904	1 415828	1	189	34	05104620000805	AA97220-01 05104620000805 11 N/A Serum-1 5 / Day 1 125h
11	N/A	5 / Day 1 0 125h	5437028 799	3209215 927	*1 694192	1	*AAR>(200)	35	05104620000821	AA97220-01 05104620000821 11 N/A Serum-1 5 / Day 1 125h
11	N/A	5 / Day 1 0 125h	5670700 145	4161452 255	1 362673	1	182	33	05104620000837	AA97220-01 05104620000837 11 N/A Serum-1 5 / Day 1 125h
11	N/A	6 / Day 1 0 1667h	5735109 067	4078566 165	1 406158	1	188	36	05104620000806	AA97220-01 05104620000806 11 N/A Serum-1 6 / Day 1 1667h
11	N/A	6 / Day 1 0 1667h	6834251 755	4081651 791	*1 674384	1	*AAR>(200)	38	05104620000822	AA97220-01 05104620000822 11 N/A Serum-1 6 / Day 1 1667h
11	N/A	6 / Day 1 0 1667h	5362138 109	3929282 158	1 364661	1	182	37	05104620000838	AA97220-01 05104620000838 11 N/A Serum-1 6 / Day 1 1667h
11	N/A	7 / Day 1 0 25h	5429479 625	3939876 02	1 378084	1	184	39	05104620000807	AA97220-01 05104620000807 11 N/A Serum-1 7 / Day 1 25h
11	N/A	7 / Day 1 0 25h	7695429 381	4713086 86	*1 632779	1	*AAR>(200)	42	05104620000823	AA97220-01 05104620000823 11 N/A Serum-1 7 / Day 1 25h
11	N/A	7 / Day 1 0 25h	5615190 066	4086544 596	1 374068	1	184	40	05104620000839	AA97220-01 05104620000839 11 N/A Serum-1 7 / Day 1 25h
11	N/A	8 / Day 1 0 333h	5393346 906	3904847 943	1 381193	1	185	44	05104620000808	AA97220-01 05104620000808 11 N/A Serum-1 8 / Day 1 333h
11	N/A	8 / Day 1 0 333h	6692383 762	4038453 256	*1 657165	1	*AAR>(200)	43	05104620000824	AA97220-01 05104620000824 11 N/A Serum-1 8 / Day 1 333h
11	N/A	8 / Day 1 0 333h	5304799 129	3865419 908	1 372373	1	183	45	05104620000840	AA97220-01 05104620000840 11 N/A Serum-1 8 / Day 1 333h
11	N/A	9 / Day 1 0 5h	5373937 804	3955079 8	1 358743	1	182	46	05104620000809	AA97220-01 05104620000809 11 N/A Serum-1 9 / Day 1 5h
11	N/A	9 / Day 1 0 5h	7263596 547	4317491 225	*1 682365	1	*AAR>(200)	47	05104620000825	AA97220-01 05104620000825 11 N/A Serum-1 9 / Day 1 5h
11	N/A	9 / Day 1 0 5h	4933940 68	3561518 112	1 385348	1	185	48	05104620000841	AA97220-01 05104620000841 11 N/A Serum-1 9 / Day 1 5h
11	N/A	10 / Day 1 0 75h	5635877 831	4142178 08	1 360607	1	182	49	05104620000810	AA97220-01 05104620000810 11 N/A Serum-1 10 / Day 1 75h
11	N/A	10 / Day 1 0 75h	6442026 099	3675814 501	*1 752544	1	*AAR>(200)	51	05104620000826	AA97220-01 05104620000826 11 N/A Serum-1 10 / Day 1 75h
11	N/A	10 / Day 1 0 75h	5869963 415	4211012 258	1 393955	1	186	50	05104620000842	AA97220-01 05104620000842 11 N/A Serum-1 10 / Day 1 75h
11	N/A	11 / Day 1 1h	6614770 187	4838082 868	1 367230	1	183	54	05104620000811	AA97220-01 05104620000811 11 N/A Serum-1 11 / Day 1 1h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
11	N/A	11 / Day 1 1h	5429501 662	3068107 681	*1 769658	1	*AAR>(200)	55	05104620000827	AA97220-01 05104620000827 11 N/A Serum-1 11 / Day 1 1h
11	N/A	11 / Day 1 1h	5655370 91	4018238 325	1 407425	1	188	53	05104620000843	AA97220-01 05104620000843 11 N/A Serum-1 11 / Day 1 1h
11	N/A	12 / Day 1 1 25h	5387285 595	3893830 564	1 383544	1	185	58	05104620000812	AA97220-01 05104620000812 11 N/A Serum-1 12 / Day 1 1 25h
11	N/A	12 / Day 1 1 25h	6853001 04	4104489 607	*1 669635	1	*AAR>(200)	57	05104620000828	AA97220-01 05104620000828 11 N/A Serum-1 12 / Day 1 1 25h
11	N/A	12 / Day 1 1 25h	5804060 347	4103975 931	1 414253	1	189	56	05104620000844	AA97220-01 05104620000844 11 N/A Serum-1 12 / Day 1 1 25h
11	N/A	13 / Day 1 1 5h	5971060 366	4255813 235	1 403036	1	187	61	05104620000813	AA97220-01 05104620000813 11 N/A Serum-1 13 / Day 1 1 5h
11	N/A	13 / Day 1 1 5h	6884116 141	4120551 221	*1 670678	1	*AAR>(200)	60	05104620000829	AA97220-01 05104620000829 11 N/A Serum-1 13 / Day 1 1 5h
11	N/A	13 / Day 1 1 5h	5727054 873	4168465 458	1 373900	1	184	59	05104620000845	AA97220-01 05104620000845 11 N/A Serum-1 13 / Day 1 1 5h
11	N/A	14 / Day 1 2h	5331537 156	3818465 734	1 396251	1	187	65	05104620000814	AA97220-01 05104620000814 11 N/A Serum-1 14 / Day 1 2h
11	N/A	14 / Day 1 2h	6877472 825	4093217 556	*1 680212	1	*AAR>(200)	64	05104620000830	AA97220-01 05104620000830 11 N/A Serum-1 14 / Day 1 2h
11	N/A	14 / Day 1 2h	6749013 678	4931081 487	1 368668	1	183	62	05104620000846	AA97220-01 05104620000846 11 N/A Serum-1 14 / Day 1 2h
11	N/A	15 / Day 1 2 5h	6182623 067	4527506 584	1 365569	1	182	68	05104620000815	AA97220-01 05104620000815 11 N/A Serum-1 15 / Day 1 2 5h
11	N/A	15 / Day 1 2 5h	6942649 317	4232396 682	*1 640359	1	*AAR>(200)	66	05104620000831	AA97220-01 05104620000831 11 N/A Serum-1 15 / Day 1 2 5h
11	N/A	15 / Day 1 2 5h	6490117 013	4761354 679	1 363082	1	182	67	05104620000847	AA97220-01 05104620000847 11 N/A Serum-1 15 / Day 1 2 5h
11	N/A	16 / Day 1 3h	5836556 26	4340594 214	1 344645	1	180	71	05104620000816	AA97220-01 05104620000816 11 N/A Serum-1 16 / Day 1 3h
11	N/A	16 / Day 1 3h	7447705 536	4558764 384	*1 633711	1	*AAR>(200)	69	05104620000832	AA97220-01 05104620000832 11 N/A Serum-1 16 / Day 1 3h
11	N/A	16 / Day 1 3h	6326047 903	4860943 406	1 301403	1	174	70	05104620000848	AA97220-01 05104620000848 11 N/A Serum-1 16 / Day 1 3h
12	N/A	1 / Day 1 -0 0333h	19287181 621	5625358 541	*3 428614	1	*AAR>(200)	72	05104620000945	AA97220-01 05104620000945 12 N/A Serum-1 1 / Day 1 - 0333h
12	N/A	2 / Day 1 0h	14412933 591	3969618 005	*3 630811	1	*AAR>(200)	73	05104620000946	AA97220-01 05104620000946 12 N/A Serum-1 2 / Day 1 0h
12	N/A	3 / Day 1 0 05h	17510493 582	4878016 664	*3 589675	1	*AAR>(200)	75	05104620000947	AA97220-01 05104620000947 12 N/A Serum-1 3 / Day 1 05h
12	N/A	4 / Day 1 0 0833h	14710545 609	3933210 895	*3 740086	1	*AAR>(200)	76	05104620000948	AA97220-01 05104620000948 12 N/A Serum-1 4 / Day 1 0833h
12	N/A	5 / Day 1 0 125h	14873124 509	4055211 595	*3 667657	1	*AAR>(200)	77	05104620000949	AA97220-01 05104620000949 12 N/A Serum-1 5 / Day 1 125h
12	N/A	6 / Day 1 0 1667h	15242424 345	4098145 939	*3 719346	1	*AAR>(200)	78	05104620000950	AA97220-01 05104620000950 12 N/A Serum-1 6 / Day 1 1667h
12	N/A	7 / Day 1 0 25h	15512510 102	4228570 432	*3 668500	1	*AAR>(200)	79	05104620000951	AA97220-01 05104620000951 12 N/A Serum-1 7 / Day 1 25h
12	N/A	8 / Day 1 0 333h	15766285 4	4221481 308	*3 734776	1	*AAR>(200)	80	05104620000952	AA97220-01 05104620000952 12 N/A Serum-1 8 / Day 1 333h
12	N/A	9 / Day 1 0 5h	19784265 957	5822701 386	*3 397781	1	*AAR>(200)	81	05104620000953	AA97220-01 05104620000953 12 N/A Serum-1 9 / Day 1 5h
12	N/A	10 / Day 1 0 75h	17498619 48	4928362 899	*3 550595	1	*AAR>(200)	82	05104620000954	AA97220-01 05104620000954 12 N/A Serum-1 10 / Day 1 75h
12	N/A	11 / Day 1 1h	17621603 51	5054936 474	*3 486019	1	*AAR>(200)	83	05104620000955	AA97220-01 05104620000955 12 N/A Serum-1 11 / Day 1 1h
12	N/A	12 / Day 1 1 25h	18640837 872	5587165 799	*3 336367	1	*AAR>(200)	84	05104620000956	AA97220-01 05104620000956 12 N/A Serum-1 12 / Day 1 1 25h
12	N/A	13 / Day 1 1 5h	17967118 194	5260632 28	*3 415391	1	*AAR>(200)	85	05104620000957	AA97220-01 05104620000957 12 N/A Serum-1 13 / Day 1 1 5h
12	N/A	14 / Day 1 2h	17279752 059	5086348 166	*3 397281	1	*AAR>(200)	86	05104620000958	AA97220-01 05104620000958 12 N/A Serum-1 14 / Day 1 2h
12	N/A	15 / Day 1 2 5h	17583215 354	5210188 852	*3 374775	1	*AAR>(200)	87	05104620000959	AA97220-01 05104620000959 12 N/A Serum-1 15 / Day 1 2 5h
12	N/A	16 / Day 1 3h	18480085 881	5387568 979	*3 430134	1	*AAR>(200)	88	05104620000960	AA97220-01 05104620000960 12 N/A Serum-1 16 / Day 1 3h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1.00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

* - Sample Rejected

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 14
Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		6126 387	5257052 671	0 001165	0 0392		0 0439	15 0
9	0 00		6696 915	5418093 305	0 001236	0 0485			
10	1 00	1 00000	39775 143	4840347 077	0 008217	0 962	-3 8		
11	2 00	0 250000	88304 822	5099095 171	0 017318	2 15	7 5		
12	4 00	0 0625000	165760 6	5270542 202	0 031450	4 00	0 0		
13	8 00	0 0156250	314727 921	4987049 75	0 063109	8 15	1 9		
14	16 0	0 00390625	566145 73	4823362 537	0 117376	15 3	-4 4		
15	40 0	0 000625000	1497259 505	4971963 596	0 301140	39 3	-1 8		
16	80 0	0 000156250	3042548 917	4942757 914	0 615557	80 5	0 6		
17	160	0 0000390625	6025290 185	4805564 556	1 253815	164	2 5		
18	200	0 0000250000	7502072 744	5033689 77	1 490372	195	-2 5		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:

Slope = 0 00763950541

Intercept = 0 000865320369

R-Squared = 0 9981

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 14
Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	8225355 124	5594614 887	1 470227	1	192		193		0 6
2	0 00	8470830 623	5751246 733	1 472869	1	193				
3	0 00	7758043 876	5235045 746	1 481944	1	194				
4	0 00	8185211 596	5520786 534	1 482617	1	194				
5	0 00	8348930 508	5658358 57	1 475504	1	193				
91	0 00	7884497 931	5373233 916	1 467365	1	192				
92	0 00	7865281 372	5378006 27	1 462490	1	191				
30	3 00	116216 587	5287012 802	0 021982	1	2 76	-8 0	2 91	-3 0	7 0
63	3 00	119306 617	4941984 189	0 024141	1	3 05	1 7			
41	37 5	1459916 337	5343850 9	0 273196	1	35 6	-5 1	35 5	-5 3	0 4
74	37 5	1392386 901	5127396 971	0 271558	1	35 4	-5 6			
52	150	5376360 461	4988046 08	1 077849	1	141	-6 0	142	-5 3	0 5
89	150	5403925 844	4964008 488	1 088621	1	142	-5 3			

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)
AAR - Concentration Found is Greater than 200 (Highest Standard)

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 14
Serum, Concentration of Cotinine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
12	N/A	1 / Day 1 -0 0333h	21155992 205	4755549 188	*4 448696	1	*AAR>(200)	22	05104620000881	AA97220-01 05104620000881 12 N/A Serum-1 1 / Day 1 - 0333h
12	N/A	1 / Day 1 -0 0333h	18655214 516	4687376 226	*3 979884	1	*AAR>(200)	23	05104620000897	AA97220-01 05104620000897 12 N/A Serum-1 1 / Day 1 - 0333h
12	N/A	1 / Day 1 -0 0333h	13932011 947	4836771 888	*2 880436	1	*AAR>(200)	20	05104620000913	AA97220-01 05104620000913 12 N/A Serum-1 1 / Day 1 - 0333h
12	N/A	1 / Day 1 -0 0333h	14518150 304	4896586 871	*2 964953	1	*AAR>(200)	21	05104620000929	AA97220-01 05104620000929 12 N/A Serum-1 1 / Day 1 - 0333h
12	N/A	2 / Day 1 0h	21910802 011	4989293 211	*4 391564	1	*AAR>(200)	26	05104620000882	AA97220-01 05104620000882 12 N/A Serum-1 2 / Day 1 0h
12	N/A	2 / Day 1 0h	18654177 622	4651448 023	*4 010402	1	*AAR>(200)	25	05104620000898	AA97220-01 05104620000898 12 N/A Serum-1 2 / Day 1 0h
12	N/A	2 / Day 1 0h	13763168 885	4798614 189	*2 868155	1	*AAR>(200)	24	05104620000914	AA97220-01 05104620000914 12 N/A Serum-1 2 / Day 1 0h
12	N/A	2 / Day 1 0h	14705116 325	4993316 435	*2 944960	1	*AAR>(200)	27	05104620000930	AA97220-01 05104620000930 12 N/A Serum-1 2 / Day 1 0h
12	N/A	3 / Day 1 0 05h	21790027 179	4981460 286	*4 374225	1	*AAR>(200)	28	05104620000883	AA97220-01 05104620000883 12 N/A Serum-1 3 / Day 1 05h
12	N/A	3 / Day 1 0 05h	19916752 767	5147363 831	*3 869311	1	*AAR>(200)	31	05104620000899	AA97220-01 05104620000899 12 N/A Serum-1 3 / Day 1 05h
12	N/A	3 / Day 1 0 05h	15303842 704	5273169 534	*2 902209	1	*AAR>(200)	32	05104620000915	AA97220-01 05104620000915 12 N/A Serum-1 3 / Day 1 05h
12	N/A	3 / Day 1 0 05h	14607133 126	5067374 03	*2 882584	1	*AAR>(200)	29	05104620000931	AA97220-01 05104620000931 12 N/A Serum-1 3 / Day 1 05h
12	N/A	4 / Day 1 0 0833h	21886208 03	5053741 16	*4 330694	1	*AAR>(200)	36	05104620000884	AA97220-01 05104620000884 12 N/A Serum-1 4 / Day 1 0833h
12	N/A	4 / Day 1 0 0833h	19706552 706	5027373 747	*3 919850	1	*AAR>(200)	34	05104620000900	AA97220-01 05104620000900 12 N/A Serum-1 4 / Day 1 0833h
12	N/A	4 / Day 1 0 0833h	14930245 263	5247534 803	*2 845192	1	*AAR>(200)	35	05104620000916	AA97220-01 05104620000916 12 N/A Serum-1 4 / Day 1 0833h
12	N/A	4 / Day 1 0 0833h	14830418 562	5057410 856	*2 932413	1	*AAR>(200)	33	05104620000932	AA97220-01 05104620000932 12 N/A Serum-1 4 / Day 1 0833h
12	N/A	5 / Day 1 0 125h	21519370 004	4917886 822	*4 375735	1	*AAR>(200)	37	05104620000885	AA97220-01 05104620000885 12 N/A Serum-1 5 / Day 1 125h
12	N/A	5 / Day 1 0 125h	19489827 991	4865544 995	*4 005682	1	*AAR>(200)	38	05104620000901	AA97220-01 05104620000901 12 N/A Serum-1 5 / Day 1 125h
12	N/A	5 / Day 1 0 125h	14507662 965	5027321 146	*2 885764	1	*AAR>(200)	39	05104620000917	AA97220-01 05104620000917 12 N/A Serum-1 5 / Day 1 125h
12	N/A	5 / Day 1 0 125h	15012016 46	5078452 847	*2 956022	1	*AAR>(200)	40	05104620000933	AA97220-01 05104620000933 12 N/A Serum-1 5 / Day 1 125h
12	N/A	6 / Day 1 0 1667h	22124184 048	5065039 97	*4 368018	1	*AAR>(200)	42	05104620000886	AA97220-01 05104620000886 12 N/A Serum-1 6 / Day 1 1667h
12	N/A	6 / Day 1 0 1667h	19544407 025	4916124 317	*3 975572	1	*AAR>(200)	44	05104620000902	AA97220-01 05104620000902 12 N/A Serum-1 6 / Day 1 1667h
12	N/A	6 / Day 1 0 1667h	14468215 884	4993369 206	*2 897486	1	*AAR>(200)	45	05104620000918	AA97220-01 05104620000918 12 N/A Serum-1 6 / Day 1 1667h
12	N/A	6 / Day 1 0 1667h	14706975 082	5008373 101	*2 936478	1	*AAR>(200)	43	05104620000934	AA97220-01 05104620000934 12 N/A Serum-1 6 / Day 1 1667h
12	N/A	7 / Day 1 0 25h	22068480 54	5124935 254	*4 306099	1	*AAR>(200)	49	05104620000887	AA97220-01 05104620000887 12 N/A Serum-1 7 / Day 1 25h
12	N/A	7 / Day 1 0 25h	19246168 784	4910409 143	*3 919463	1	*AAR>(200)	48	05104620000903	AA97220-01 05104620000903 12 N/A Serum-1 7 / Day 1 25h
12	N/A	7 / Day 1 0 25h	14297457 548	4963210 288	*2 880687	1	*AAR>(200)	47	05104620000919	AA97220-01 05104620000919 12 N/A Serum-1 7 / Day 1 25h
12	N/A	7 / Day 1 0 25h	14901891 58	5047156 427	*2 952532	1	*AAR>(200)	46	05104620000935	AA97220-01 05104620000935 12 N/A Serum-1 7 / Day 1 25h
12	N/A	8 / Day 1 0 333h	20951415 636	4886692 403	*4 287443	1	*AAR>(200)	51	05104620000888	AA97220-01 05104620000888 12 N/A Serum-1 8 / Day 1 333h
12	N/A	8 / Day 1 0 333h	19286862 953	5067227 035	*3 806197	1	*AAR>(200)	53	05104620000904	AA97220-01 05104620000904 12 N/A Serum-1 8 / Day 1 333h
12	N/A	8 / Day 1 0 333h	15242294 365	5245233 335	*2 905933	1	*AAR>(200)	54	05104620000920	AA97220-01 05104620000920 12 N/A Serum-1 8 / Day 1 333h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
12	N/A	8 / Day 1 0 333h	14543381 396	4995526 233	*2 911281	1	*AAR>(200)	50	05104620000936	AA97220-01 05104620000936 12 N/A Serum-1 8 / Day 1 333h
12	N/A	9 / Day 1 0 5h	21127466 249	4863485 195	*4 344100	1	*AAR>(200)	58	05104620000889	AA97220-01 05104620000889 12 N/A Serum-1 9 / Day 1 5h
12	N/A	9 / Day 1 0 5h	18990487 52	4918513 512	*3 861022	1	*AAR>(200)	57	05104620000905	AA97220-01 05104620000905 12 N/A Serum-1 9 / Day 1 5h
12	N/A	9 / Day 1 0 5h	13668591 481	4940894 59	*2 766420	1	*AAR>(200)	56	05104620000921	AA97220-01 05104620000921 12 N/A Serum-1 9 / Day 1 5h
12	N/A	9 / Day 1 0 5h	14907986 982	5250581 933	*2 839302	1	*AAR>(200)	55	05104620000937	AA97220-01 05104620000937 12 N/A Serum-1 9 / Day 1 5h
12	N/A	10 / Day 1 0 75h	21404378 005	4899942 285	*4 368292	1	*AAR>(200)	61	05104620000890	AA97220-01 05104620000890 12 N/A Serum-1 10 / Day 1 75h
12	N/A	10 / Day 1 0 75h	18167324 153	4727016 457	*3 843296	1	*AAR>(200)	62	05104620000906	AA97220-01 05104620000906 12 N/A Serum-1 10 / Day 1 75h
12	N/A	10 / Day 1 0 75h	13544252 094	4723656 36	*2 867324	1	*AAR>(200)	60	05104620000922	AA97220-01 05104620000922 12 N/A Serum-1 10 / Day 1 75h
12	N/A	10 / Day 1 0 75h	14613435 553	4850140 726	*3 012992	1	*AAR>(200)	59	05104620000938	AA97220-01 05104620000938 12 N/A Serum-1 10 / Day 1 75h
12	N/A	11 / Day 1 1h	21267772 991	4892471 079	*4 347041	1	*AAR>(200)	64	05104620000891	AA97220-01 05104620000891 12 N/A Serum-1 11 / Day 1 1h
12	N/A	11 / Day 1 1h	18909969 312	4873276 203	*3 880340	1	*AAR>(200)	67	05104620000907	AA97220-01 05104620000907 12 N/A Serum-1 11 / Day 1 1h
12	N/A	11 / Day 1 1h	14567650 484	5030328 417	*2 895964	1	*AAR>(200)	66	05104620000923	AA97220-01 05104620000923 12 N/A Serum-1 11 / Day 1 1h
12	N/A	11 / Day 1 1h	14027913 116	4761443 24	*2 946147	1	*AAR>(200)	65	05104620000939	AA97220-01 05104620000939 12 N/A Serum-1 11 / Day 1 1h
12	N/A	12 / Day 1 1 25h	21149205 982	4892037 197	*4 323190	1	*AAR>(200)	68	05104620000892	AA97220-01 05104620000892 12 N/A Serum-1 12 / Day 1 1 25h
12	N/A	12 / Day 1 1 25h	18619250 013	4882684 479	*3 813322	1	*AAR>(200)	71	05104620000908	AA97220-01 05104620000908 12 N/A Serum-1 12 / Day 1 1 25h
12	N/A	12 / Day 1 1 25h	14112400 356	4842796 915	*2 914101	1	*AAR>(200)	70	05104620000924	AA97220-01 05104620000924 12 N/A Serum-1 12 / Day 1 1 25h
12	N/A	12 / Day 1 1 25h	14232286 741	4961007 179	*2 868830	1	*AAR>(200)	69	05104620000940	AA97220-01 05104620000940 12 N/A Serum-1 12 / Day 1 1 25h
12	N/A	13 / Day 1 1 5h	20640498 976	4775848 178	*4 321850	1	*AAR>(200)	75	05104620000893	AA97220-01 05104620000893 12 N/A Serum-1 13 / Day 1 1 5h
12	N/A	13 / Day 1 1 5h	17686240 302	4734592 952	*3 735536	1	*AAR>(200)	73	05104620000909	AA97220-01 05104620000909 12 N/A Serum-1 13 / Day 1 1 5h
12	N/A	13 / Day 1 1 5h	14821720 168	5104498 548	*2 903658	1	*AAR>(200)	72	05104620000925	AA97220-01 05104620000925 12 N/A Serum-1 13 / Day 1 1 5h
12	N/A	13 / Day 1 1 5h	14378139 125	5023622 782	*2 862106	1	*AAR>(200)	76	05104620000941	AA97220-01 05104620000941 12 N/A Serum-1 13 / Day 1 1 5h
12	N/A	14 / Day 1 2h	21189824 347	4930495 073	*4 297707	1	*AAR>(200)	78	05104620000894	AA97220-01 05104620000894 12 N/A Serum-1 14 / Day 1 2h
12	N/A	14 / Day 1 2h	18256801 875	4907004 585	*3 720559	1	*AAR>(200)	80	05104620000910	AA97220-01 05104620000910 12 N/A Serum-1 14 / Day 1 2h
12	N/A	14 / Day 1 2h	14070025 584	4862404 895	*2 893635	1	*AAR>(200)	79	05104620000926	AA97220-01 05104620000926 12 N/A Serum-1 14 / Day 1 2h
12	N/A	14 / Day 1 2h	14506065 835	4938254 996	*2 937488	1	*AAR>(200)	77	05104620000942	AA97220-01 05104620000942 12 N/A Serum-1 14 / Day 1 2h
12	N/A	15 / Day 1 2 5h	20994411 645	4990439 007	*4 206927	1	*AAR>(200)	81	05104620000895	AA97220-01 05104620000895 12 N/A Serum-1 15 / Day 1 2 5h
12	N/A	15 / Day 1 2 5h	18189807 214	4924045 757	*3 694078	1	*AAR>(200)	84	05104620000911	AA97220-01 05104620000911 12 N/A Serum-1 15 / Day 1 2 5h
12	N/A	15 / Day 1 2 5h	14440019 47	4989913 484	*2 893842	1	*AAR>(200)	83	05104620000927	AA97220-01 05104620000927 12 N/A Serum-1 15 / Day 1 2 5h
12	N/A	15 / Day 1 2 5h	14849637 792	5183283 792	*2 864909	1	*AAR>(200)	82	05104620000943	AA97220-01 05104620000943 12 N/A Serum-1 15 / Day 1 2 5h
12	N/A	16 / Day 1 3h	21172617 451	5000555 72	*4 234053	1	*AAR>(200)	86	05104620000896	AA97220-01 05104620000896 12 N/A Serum-1 16 / Day 1 3h
12	N/A	16 / Day 1 3h	18300167 368	5026138 953	*3 640999	1	*AAR>(200)	88	05104620000912	AA97220-01 05104620000912 12 N/A Serum-1 16 / Day 1 3h
12	N/A	16 / Day 1 3h	14810269 618	5160218 641	*2 870086	1	*AAR>(200)	87	05104620000928	AA97220-01 05104620000928 12 N/A Serum-1 16 / Day 1 3h
12	N/A	16 / Day 1 3h	14030958 183	4923563 655	*2 849757	1	*AAR>(200)	85	05104620000944	AA97220-01 05104620000944 12 N/A Serum-1 16 / Day 1 3h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1.00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

* - Sample Rejected

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 16
 Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		0	260139 254	0 000000	-0 0241		-0 0241	0 0
9	0 00		0	259590 437	0 000000	-0 0241			
10	1 00	1 00000	14457 507	269088 482	0 053728	0 942	-5 8		
11	2 00	0 250000	30080 713	244851 051	0 122853	2 19	9 5		
12	4 00	0 0625000	50490 187	220473 861	0 229008	4 10	2 5		
13	8 00	0 0156250	94443 005	202065 411	0 467388	8 38	4 8		
14	16 0	0 00390625	209315 429	236185 81	0 886232	15 9	-0 6		
15	40 0	0 000625000	446660 743	201860 132	2 212724	39 8	-0 5		
16	80 0	0 000156250	966108 91	215573 37	4 481578	80 6	0 8		
17	160	0 0000390625	2003313 388	234791 31	8 532315	153	-4 4		
18	200	0 0000250000	2277105 025	218707 175	10 411661	187	-6 5		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:

Slope = 0 0555866526

Intercept = 0 00134057930

R-Squared = 0 9966

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 16
Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	2911208 755	265381 17	10 969915	1	197		193		2 0
2	0 00	2544246 423	232388 454	10 948248	1	197				
3	0 00	2508946 669	234983 044	10 677139	1	192				
4	0 00	2498991 695	239958 046	10 414286	1	187				
5	0 00	2615971 322	244421 054	10 702725	1	193				
90	0 00	4106026 809	375710 89	10 928687	1	197				
91	0 00	4438693 177	417096 304	10 641890	1	191				
30	3 00	87399 68	572477 278	*0 152669	1	*2 72				
63	3 00	26187 488	143104 167	0 182996	1	3 27	9 0			
41	37 5	677233 602	353181 481	1 917523	1	34 5	-8 0	34 9	-6 9	1 4
74	37 5	394474 329	201683 617	1 955907	1	35 2	-6 1			
52	150	1257581 041	168942 344	7 443847	1	134	-10 7			
88	150	3984613 714	506808 233	*7 862172	1	*141				

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)
AAR - Concentration Found is Greater than 200 (Highest Standard)

Reason for Deactivation of Sample
* UISR

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 16
Serum, Concentration of Cotinine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
13	N/A	1 / Day 1 -0 0333h	1996483 796	219086 872	9 112750	1	164	20	05104620000961	AA97220-01 05104620000961 13 N/A Serum-1 1 / Day 1 - 0333h
13	N/A	2 / Day 1 0h	2328076 349	242744 274	9 590654	1	173	21	05104620000962	AA97220-01 05104620000962 13 N/A Serum-1 2 / Day 1 0h
13	N/A	3 / Day 1 0 05h	2206779 179	236578 798	9 327882	1	168	22	05104620000963	AA97220-01 05104620000963 13 N/A Serum-1 3 / Day 1 05h
13	N/A	4 / Day 1 0 0833h	2166041 475	231427 589	9 359478	1	168	23	05104620000964	AA97220-01 05104620000964 13 N/A Serum-1 4 / Day 1 0833h
13	N/A	5 / Day 1 0 125h	2290204 674	246346 759	9 296671	1	167	24	05104620000965	AA97220-01 05104620000965 13 N/A Serum-1 5 / Day 1 125h
13	N/A	6 / Day 1 0 1667h	2243307 528	246984 801	9 082776	1	163	25	05104620000966	AA97220-01 05104620000966 13 N/A Serum-1 6 / Day 1 1667h
13	N/A	7 / Day 1 0 25h	2722813 171	286142 648	9 515580	1	171	26	05104620000967	AA97220-01 05104620000967 13 N/A Serum-1 7 / Day 1 25h
13	N/A	8 / Day 1 0 333h	2779415 006	290520 796	9 567009	1	172	27	05104620000968	AA97220-01 05104620000968 13 N/A Serum-1 8 / Day 1 333h
13	N/A	9 / Day 1 0 5h	3049654 816	324470 268	9 398873	1	169	28	05104620000969	AA97220-01 05104620000969 13 N/A Serum-1 9 / Day 1 5h
13	N/A	10 / Day 1 0 75h	3850892 104	413662 741	9 309255	1	167	29	05104620000970	AA97220-01 05104620000970 13 N/A Serum-1 10 / Day 1 75h
13	N/A	11 / Day 1 1h	5836985 913	605897 446	*9 633620	1	*173	31	05104620000971	AA97220-01 05104620000971 13 N/A Serum-1 11 / Day 1 1h
13	N/A	12 / Day 1 1 25h	1561801 204	167614 457	9 317819	1	168	32	05104620000972	AA97220-01 05104620000972 13 N/A Serum-1 12 / Day 1 1 25h
13	N/A	13 / Day 1 1 5h	1394082 229	155470 19	8 966878	1	161	33	05104620000973	AA97220-01 05104620000973 13 N/A Serum-1 13 / Day 1 1 5h
13	N/A	14 / Day 1 2h	1500834 692	174112 277	8 619925	1	155	34	05104620000974	AA97220-01 05104620000974 13 N/A Serum-1 14 / Day 1 2h
13	N/A	15 / Day 1 2 5h	2076433 202	243642 618	8 522455	1	153	35	05104620000975	AA97220-01 05104620000975 13 N/A Serum-1 15 / Day 1 2 5h
13	N/A	16 / Day 1 3h	1955013 717	232221 007	8 418763	1	151	36	05104620000976	AA97220-01 05104620000976 13 N/A Serum-1 16 / Day 1 3h
14	N/A	1 / Day 1 -0 0333h	3567904 121	243968 515	*14 624445	1	*AAR>(200)	38	05104620001073	AA97220-01 05104620001073 14 N/A Serum-1 1 / Day 1 - 0333h
14	N/A	1 / Day 1 -0 0333h	2818752 329	214521 268	*13 139734	1	*AAR>(200)	39	05104620001089	AA97220-01 05104620001089 14 N/A Serum-1 1 / Day 1 - 0333h
14	N/A	1 / Day 1 -0 0333h	3659016 816	267929 021	*13 656665	1	*AAR>(200)	37	05104620001105	AA97220-01 05104620001105 14 N/A Serum-1 1 / Day 1 - 0333h
14	N/A	2 / Day 1 0h	4886727 727	335754 812	*14 554453	1	*AAR>(200)	43	05104620001074	AA97220-01 05104620001074 14 N/A Serum-1 2 / Day 1 0h
14	N/A	2 / Day 1 0h	4524583 131	342461 403	*13 211951	1	*AAR>(200)	40	05104620001090	AA97220-01 05104620001090 14 N/A Serum-1 2 / Day 1 0h
14	N/A	2 / Day 1 0h	5273103 974	374456 045	*14 082037	1	*AAR>(200)	42	05104620001106	AA97220-01 05104620001106 14 N/A Serum-1 2 / Day 1 0h
14	N/A	3 / Day 1 0 05h	2471914 271	173820 796	*14 221050	1	*AAR>(200)	46	05104620001075	AA97220-01 05104620001075 14 N/A Serum-1 3 / Day 1 05h
14	N/A	3 / Day 1 0 05h	5444231 054	405711 369	*13 418976	1	*AAR>(200)	44	05104620001091	AA97220-01 05104620001091 14 N/A Serum-1 3 / Day 1 05h
14	N/A	3 / Day 1 0 05h	6090172 058	448089 899	*13 591407	1	*AAR>(200)	45	05104620001107	AA97220-01 05104620001107 14 N/A Serum-1 3 / Day 1 05h
14	N/A	4 / Day 1 0 0833h	2206202 447	150208 25	*14 687625	1	*AAR>(200)	48	05104620001076	AA97220-01 05104620001076 14 N/A Serum-1 4 / Day 1 0833h
14	N/A	4 / Day 1 0 0833h	2380515 978	189298 689	*12 575449	1	*AAR>(200)	49	05104620001092	AA97220-01 05104620001092 14 N/A Serum-1 4 / Day 1 0833h
14	N/A	4 / Day 1 0 0833h	2255998 843	160936 075	*14 017981	1	*AAR>(200)	47	05104620001108	AA97220-01 05104620001108 14 N/A Serum-1 4 / Day 1 0833h
14	N/A	5 / Day 1 0 125h	2615961 687	192753 793	*13 571519	1	*AAR>(200)	53	05104620001077	AA97220-01 05104620001077 14 N/A Serum-1 5 / Day 1 125h
14	N/A	5 / Day 1 0 125h	2311476 254	178089 405	*12 979302	1	*AAR>(200)	50	05104620001093	AA97220-01 05104620001093 14 N/A Serum-1 5 / Day 1 125h
14	N/A	5 / Day 1 0 125h	2765581 439	195278 692	*14 162228	1	*AAR>(200)	51	05104620001109	AA97220-01 05104620001109 14 N/A Serum-1 5 / Day 1 125h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
14	N/A	6 / Day 1 0 1667h	2829103 479	198653 081	*14 241428	1	*AAR>(200)	54	05104620001078	AA97220-01 05104620001078 14 N/A Serum-1 6 / Day 1 1667h
14	N/A	6 / Day 1 0 1667h	2231553 555	170991 298	*13 050685	1	*AAR>(200)	56	05104620001094	AA97220-01 05104620001094 14 N/A Serum-1 6 / Day 1 1667h
14	N/A	6 / Day 1 0 1667h	2679175 165	179857 547	*14 896095	1	*AAR>(200)	55	05104620001110	AA97220-01 05104620001110 14 N/A Serum-1 6 / Day 1 1667h
14	N/A	7 / Day 1 0 25h	2488706 063	171798 549	*14 486188	1	*AAR>(200)	58	05104620001079	AA97220-01 05104620001079 14 N/A Serum-1 7 / Day 1 25h
14	N/A	7 / Day 1 0 25h	1964764 316	145682 498	*13 486619	1	*AAR>(200)	59	05104620001095	AA97220-01 05104620001095 14 N/A Serum-1 7 / Day 1 25h
14	N/A	7 / Day 1 0 25h	2184777 236	152067 993	*14 367108	1	*AAR>(200)	57	05104620001111	AA97220-01 05104620001111 14 N/A Serum-1 7 / Day 1 25h
14	N/A	8 / Day 1 0 333h	2185434 215	154034 309	*14 187970	1	*AAR>(200)	60	05104620001080	AA97220-01 05104620001080 14 N/A Serum-1 8 / Day 1 333h
14	N/A	8 / Day 1 0 333h	1964276 878	147969 883	*13 274842	1	*AAR>(200)	61	05104620001096	AA97220-01 05104620001096 14 N/A Serum-1 8 / Day 1 333h
14	N/A	8 / Day 1 0 333h	2151796 697	152134 835	*14 144010	1	*AAR>(200)	62	05104620001112	AA97220-01 05104620001112 14 N/A Serum-1 8 / Day 1 333h
14	N/A	9 / Day 1 0 5h	2133534 36	151146 407	*14 115680	1	*AAR>(200)	64	05104620001081	AA97220-01 05104620001081 14 N/A Serum-1 9 / Day 1 5h
14	N/A	9 / Day 1 0 5h	2703891 094	218854 447	*12 354746	1	*AAR>(200)	66	05104620001097	AA97220-01 05104620001097 14 N/A Serum-1 9 / Day 1 5h
14	N/A	9 / Day 1 0 5h	2028049 916	140180 245	*14 467445	1	*AAR>(200)	65	05104620001113	AA97220-01 05104620001113 14 N/A Serum-1 9 / Day 1 5h
14	N/A	10 / Day 1 0 75h	1984662 104	138389 902	*14 341090	1	*AAR>(200)	68	05104620001082	AA97220-01 05104620001082 14 N/A Serum-1 10 / Day 1 75h
14	N/A	10 / Day 1 0 75h	1827978 56	137334 951	*13 310367	1	*AAR>(200)	69	05104620001098	AA97220-01 05104620001098 14 N/A Serum-1 10 / Day 1 75h
14	N/A	10 / Day 1 0 75h	3799265 441	257479 115	*14 755626	1	*AAR>(200)	67	05104620001114	AA97220-01 05104620001114 14 N/A Serum-1 10 / Day 1 75h
14	N/A	11 / Day 1 1h	2388440 136	171828 474	*13 900142	1	*AAR>(200)	72	05104620001083	AA97220-01 05104620001083 14 N/A Serum-1 11 / Day 1 1h
14	N/A	11 / Day 1 1h	1840457 718	150320 467	*12 243560	1	*AAR>(200)	70	05104620001099	AA97220-01 05104620001099 14 N/A Serum-1 11 / Day 1 1h
14	N/A	11 / Day 1 1h	2128118 735	142501 272	*14 934033	1	*AAR>(200)	71	05104620001115	AA97220-01 05104620001115 14 N/A Serum-1 11 / Day 1 1h
14	N/A	12 / Day 1 1 25h	2425180 322	173941 181	*13 942531	1	*AAR>(200)	75	05104620001084	AA97220-01 05104620001084 14 N/A Serum-1 12 / Day 1 1 25h
14	N/A	12 / Day 1 1 25h	2282018 105	166652 078	*13 693307	1	*AAR>(200)	73	05104620001116	AA97220-01 05104620001116 14 N/A Serum-1 12 / Day 1 1 25h
14	N/A	13 / Day 1 1 5h	4674799 786	333617 72	*14 012445	1	*AAR>(200)	78	05104620001085	AA97220-01 05104620001085 14 N/A Serum-1 13 / Day 1 1 5h
14	N/A	13 / Day 1 1 5h	4864555 655	394484 271	*12 331431	1	*AAR>(200)	76	05104620001101	AA97220-01 05104620001101 14 N/A Serum-1 13 / Day 1 1 5h
14	N/A	13 / Day 1 1 5h	4358580 676	311321 724	*14 000246	1	*AAR>(200)	77	05104620001117	AA97220-01 05104620001117 14 N/A Serum-1 13 / Day 1 1 5h
14	N/A	14 / Day 1 2h	4755957 915	348496 167	*13 647088	1	*AAR>(200)	80	05104620001086	AA97220-01 05104620001086 14 N/A Serum-1 14 / Day 1 2h
14	N/A	14 / Day 1 2h	3646210 78	308184 741	*11 831250	1	*AAR>(200)	81	05104620001102	AA97220-01 05104620001102 14 N/A Serum-1 14 / Day 1 2h
14	N/A	14 / Day 1 2h	4937771 613	346961 866	*14 231453	1	*AAR>(200)	79	05104620001118	AA97220-01 05104620001118 14 N/A Serum-1 14 / Day 1 2h
14	N/A	15 / Day 1 2 5h	6416006 969	504058 912	*12 728685	1	*AAR>(200)	84	05104620001087	AA97220-01 05104620001087 14 N/A Serum-1 15 / Day 1 2 5h
14	N/A	15 / Day 1 2 5h	6002849 257	508238 414	*11 811089	1	*AAR>(200)	83	05104620001103	AA97220-01 05104620001103 14 N/A Serum-1 15 / Day 1 2 5h
14	N/A	15 / Day 1 2 5h	4876922 437	346516 827	*14 074129	1	*AAR>(200)	82	05104620001119	AA97220-01 05104620001119 14 N/A Serum-1 15 / Day 1 2 5h
14	N/A	16 / Day 1 3h	6667817 215	529535 346	*12 591827	1	*AAR>(200)	87	05104620001088	AA97220-01 05104620001088 14 N/A Serum-1 16 / Day 1 3h
14	N/A	16 / Day 1 3h	5719277 003	475621 306	*12 024855	1	*AAR>(200)	85	05104620001104	AA97220-01 05104620001104 14 N/A Serum-1 16 / Day 1 3h
14	N/A	16 / Day 1 3h	6707649 855	503458 473	*13 323144	1	*AAR>(200)	86	05104620001120	AA97220-01 05104620001120 14 N/A Serum-1 16 / Day 1 3h

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1.00 (Lowest Standard)
AAR - Concentration Found is Greater than 200 (Highest Standard)

* - Sample Rejected

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 17
Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		0	224330 214	0 000000	-0 0725		-0 0144	-570 8
9	0 00		1563 663	240681 966	0 006497	0 0437			
10	1 00	1 00000	13152 748	222352 596	0 059153	0 985	-1 5		
11	2 00	0 250000	25410 436	210047 139	0 120975	2 09	4 5		
12	4 00	0 0625000	50361 952	224360 324	0 224469	3 94	-1 5		
13	8 00	0 0156250	87961 792	198611 952	0 442883	7 84	-2 0		
14	16 0	0 00390625	188209 615	216333 982	0 869996	15 5	-3 1		
15	40 0	0 000625000	541819 585	236538 747	2 290617	40 9	2 3		
16	80 0	0 000156250	1000101 504	221003 337	4 525278	80 8	1 0		
17	160	0 0000390625	2027624 102	226771 875	8 941250	160	0 0		
18	200	0 0000250000	2131998 863	189317 18	11 261518	201	0 5		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:

Slope = 0 0559404647

Intercept = 0 00405311285

R-Squared = 0 9992

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 17
 Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	2849855 169	264485 011	10 775110	1	193		193		3 7
2	0 00	2732380 089	253420 93	10 781983	1	193				
3	0 00	2319132 228	224066 26	10 350207	1	185				
4	0 00	1981369 019	186212 981	10 640338	1	190				
5	0 00	2191210 651	207878 622	10 540818	1	188				
91	0 00	2358180 085	203504 968	11 587826	1	207				
92	0 00	2037562 628	186962 921	10 898218	1	195				
30	3 00	34756 542	195639 152	0 177656	1	3 10	3 3	3 03	1 0	3 5
63	3 00	35243 033	208424 748	0 169092	1	2 95	-1 7			
41	37 5	454293 774	224046 457	2 027677	1	36 2	-3 5	36 6	-2 4	1 5
74	37 5	618826 1	298164 694	2 075451	1	37 0	-1 3			
52	150	1736605 553	204507 645	8 491641	1	152	1 3	148	-1 3	4 3
89	150	2611987 944	325564 157	8 022959	1	143	-4 7			

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)
 AAR - Concentration Found is Greater than 200 (Highest Standard)

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 17
Serum, Concentration of Cotinine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
14	N/A	1 / Day 1 -0 0333h	2653915 408	212843 868	*12 468837	1	*AAR>(200)	21	05104620001041	AA97220-01 05104620001041 14 N/A Serum-1 1 / Day 1 - 0333h
14	N/A	1 / Day 1 -0 0333h	2491821 865	200945 81	*12 400467	1	*AAR>(200)	20	05104620001057	AA97220-01 05104620001057 14 N/A Serum-1 1 / Day 1 - 0333h
14	N/A	2 / Day 1 0h	2410915 297	199900 39	*12 060583	1	*AAR>(200)	22	05104620001042	AA97220-01 05104620001042 14 N/A Serum-1 2 / Day 1 0h
14	N/A	2 / Day 1 0h	2431778 652	222618 07	10 923546	1	195	23	05104620001058	AA97220-01 05104620001058 14 N/A Serum-1 2 / Day 1 0h
14	N/A	3 / Day 1 0 05h	3099262 793	248941 457	*12 449766	1	*AAR>(200)	25	05104620001043	AA97220-01 05104620001043 14 N/A Serum-1 3 / Day 1 05h
14	N/A	3 / Day 1 0 05h	2684960 442	241710 53	11 108165	1	198	24	05104620001059	AA97220-01 05104620001059 14 N/A Serum-1 3 / Day 1 05h
14	N/A	4 / Day 1 0 0833h	2698362 259	217716 001	*12 393955	1	*AAR>(200)	26	05104620001044	AA97220-01 05104620001044 14 N/A Serum-1 4 / Day 1 0833h
14	N/A	4 / Day 1 0 0833h	2371129 29	184781 543	*12 832068	1	*AAR>(200)	27	05104620001060	AA97220-01 05104620001060 14 N/A Serum-1 4 / Day 1 0833h
14	N/A	5 / Day 1 0 125h	2498254 096	200988 585	*12 429831	1	*AAR>(200)	28	05104620001045	AA97220-01 05104620001045 14 N/A Serum-1 5 / Day 1 125h
14	N/A	5 / Day 1 0 125h	2542985 44	237455 685	10 709305	1	191	29	05104620001061	AA97220-01 05104620001061 14 N/A Serum-1 5 / Day 1 125h
14	N/A	6 / Day 1 0 1667h	4837171 522	388560 412	*12 448956	1	*AAR>(200)	32	05104620001046	AA97220-01 05104620001046 14 N/A Serum-1 6 / Day 1 1667h
14	N/A	6 / Day 1 0 1667h	2750186 981	246509 478	11 156516	1	199	31	05104620001062	AA97220-01 05104620001062 14 N/A Serum-1 6 / Day 1 1667h
14	N/A	7 / Day 1 0 25h	2156696 602	172992 364	*12 467005	1	*AAR>(200)	34	05104620001047	AA97220-01 05104620001047 14 N/A Serum-1 7 / Day 1 25h
14	N/A	7 / Day 1 0 25h	2477577 622	227732 541	10 879331	1	194	33	05104620001063	AA97220-01 05104620001063 14 N/A Serum-1 7 / Day 1 25h
14	N/A	8 / Day 1 0 333h	2277409 681	187484 53	*12 147187	1	*AAR>(200)	35	05104620001048	AA97220-01 05104620001048 14 N/A Serum-1 8 / Day 1 333h
14	N/A	8 / Day 1 0 333h	2203981 915	195239 862	*11 288586	1	*AAR>(200)	36	05104620001064	AA97220-01 05104620001064 14 N/A Serum-1 8 / Day 1 333h
14	N/A	9 / Day 1 0 5h	2564422 305	211420 431	*12 129491	1	*AAR>(200)	37	05104620001049	AA97220-01 05104620001049 14 N/A Serum-1 9 / Day 1 5h
14	N/A	9 / Day 1 0 5h	2574154 605	230189 456	11 182765	1	200	38	05104620001065	AA97220-01 05104620001065 14 N/A Serum-1 9 / Day 1 5h
14	N/A	10 / Day 1 0 75h	2045973 635	159232 138	*12 848999	1	*AAR>(200)	40	05104620001050	AA97220-01 05104620001050 14 N/A Serum-1 10 / Day 1 75h
14	N/A	10 / Day 1 0 75h	2646727 614	227513 409	*11 633282	1	*AAR>(200)	39	05104620001066	AA97220-01 05104620001066 14 N/A Serum-1 10 / Day 1 75h
14	N/A	11 / Day 1 1h	3003685 481	246908 728	*12 165165	1	*AAR>(200)	43	05104620001051	AA97220-01 05104620001051 14 N/A Serum-1 11 / Day 1 1h
14	N/A	11 / Day 1 1h	2502940 507	231364 938	10 818150	1	193	42	05104620001067	AA97220-01 05104620001067 14 N/A Serum-1 11 / Day 1 1h
14	N/A	12 / Day 1 1 25h	3182805 249	246588 538	*12 907353	1	*AAR>(200)	45	05104620001052	AA97220-01 05104620001052 14 N/A Serum-1 12 / Day 1 1 25h
14	N/A	12 / Day 1 1 25h	2584874 295	232771 528	11 104770	1	198	44	05104620001068	AA97220-01 05104620001068 14 N/A Serum-1 12 / Day 1 1 25h
14	N/A	13 / Day 1 1 5h	3351682 864	262072 798	*12 789129	1	*AAR>(200)	46	05104620001053	AA97220-01 05104620001053 14 N/A Serum-1 13 / Day 1 1 5h
14	N/A	13 / Day 1 1 5h	3139330 767	282368 659	11 117844	1	199	47	05104620001069	AA97220-01 05104620001069 14 N/A Serum-1 13 / Day 1 1 5h
14	N/A	14 / Day 1 2h	3033551 893	249051 614	*12 180415	1	*AAR>(200)	48	05104620001054	AA97220-01 05104620001054 14 N/A Serum-1 14 / Day 1 2h
14	N/A	14 / Day 1 2h	3242561 022	285316 86	*11 364772	1	*AAR>(200)	49	05104620001070	AA97220-01 05104620001070 14 N/A Serum-1 14 / Day 1 2h
14	N/A	15 / Day 1 2 5h	3188112 961	270593 146	*11 781943	1	*AAR>(200)	50	05104620001055	AA97220-01 05104620001055 14 N/A Serum-1 15 / Day 1 2 5h
14	N/A	15 / Day 1 2 5h	3254212 118	302898 978	10 743556	1	192	51	05104620001071	AA97220-01 05104620001071 14 N/A Serum-1 15 / Day 1 2 5h
14	N/A	16 / Day 1 3h	2795198 49	235350 366	*11 876754	1	*AAR>(200)	53	05104620001056	AA97220-01 05104620001056 14 N/A Serum-1 16 / Day 1 3h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
14	N/A	16 / Day 1 3h	2073102 377	200620 666	10 333444	1	185	54	05104620001072	AA97220-01 05104620001072 14 N/A Serum-1 16 / Day 1 3h
15	N/A	1 / Day 1 -0 0333h	2351304 102	155327 747	*15 137695	1	*AAR>(200)	56	05104620001169	AA97220-01 05104620001169 15 N/A Serum-1 1 / Day 1 - 0333h
15	N/A	1 / Day 1 -0 0333h	2244945 333	199160 825	*11 272023	1	*AAR>(200)	55	05104620001185	AA97220-01 05104620001185 15 N/A Serum-1 1 / Day 1 - 0333h
15	N/A	2 / Day 1 0h	3301424 405	223284 635	*14 785721	1	*AAR>(200)	58	05104620001170	AA97220-01 05104620001170 15 N/A Serum-1 2 / Day 1 0h
15	N/A	2 / Day 1 0h	2127460 773	196643 481	10 818873	1	193	57	05104620001186	AA97220-01 05104620001186 15 N/A Serum-1 2 / Day 1 0h
15	N/A	3 / Day 1 0 05h	2566100 027	176720 242	*14 520691	1	*AAR>(200)	59	05104620001171	AA97220-01 05104620001171 15 N/A Serum-1 3 / Day 1 05h
15	N/A	3 / Day 1 0 05h	2227693 702	205337 248	10 848951	1	194	60	05104620001187	AA97220-01 05104620001187 15 N/A Serum-1 3 / Day 1 05h
15	N/A	4 / Day 1 0 0833h	2971860 313	203064 248	*14 635074	1	*AAR>(200)	61	05104620001172	AA97220-01 05104620001172 15 N/A Serum-1 4 / Day 1 0833h
15	N/A	4 / Day 1 0 0833h	2542163 295	232271 568	10 944789	1	196	62	05104620001188	AA97220-01 05104620001188 15 N/A Serum-1 4 / Day 1 0833h
15	N/A	5 / Day 1 0 125h	3526727 021	236538 172	*14 909759	1	*AAR>(200)	64	05104620001173	AA97220-01 05104620001173 15 N/A Serum-1 5 / Day 1 125h
15	N/A	5 / Day 1 0 125h	1918024 63	166719 229	*11 504520	1	*AAR>(200)	65	05104620001189	AA97220-01 05104620001189 15 N/A Serum-1 5 / Day 1 125h
15	N/A	6 / Day 1 0 1667h	2855733 263	200484 59	*14 244153	1	*AAR>(200)	66	05104620001174	AA97220-01 05104620001174 15 N/A Serum-1 6 / Day 1 1667h
15	N/A	6 / Day 1 0 1667h	2408135 767	199351 494	*12 079848	1	*AAR>(200)	67	05104620001190	AA97220-01 05104620001190 15 N/A Serum-1 6 / Day 1 1667h
15	N/A	7 / Day 1 0 25h	3149285 519	216146 699	*14 570130	1	*AAR>(200)	69	05104620001175	AA97220-01 05104620001175 15 N/A Serum-1 7 / Day 1 25h
15	N/A	7 / Day 1 0 25h	2360365 653	204794 217	*11 525548	1	*AAR>(200)	68	05104620001191	AA97220-01 05104620001191 15 N/A Serum-1 7 / Day 1 25h
15	N/A	8 / Day 1 0 333h	2595260 135	177261 565	*14 640851	1	*AAR>(200)	70	05104620001176	AA97220-01 05104620001176 15 N/A Serum-1 8 / Day 1 333h
15	N/A	8 / Day 1 0 333h	2130406 785	182435 409	*11 677595	1	*AAR>(200)	71	05104620001192	AA97220-01 05104620001192 15 N/A Serum-1 8 / Day 1 333h
15	N/A	9 / Day 1 0 5h	3742454 703	244101 544	*15 331549	1	*AAR>(200)	72	05104620001177	AA97220-01 05104620001177 15 N/A Serum-1 9 / Day 1 5h
15	N/A	9 / Day 1 0 5h	3037230 466	254921 155	*11 914392	1	*AAR>(200)	73	05104620001193	AA97220-01 05104620001193 15 N/A Serum-1 9 / Day 1 5h
15	N/A	10 / Day 1 0 75h	3877974 061	254670 708	*15 227405	1	*AAR>(200)	75	05104620001178	AA97220-01 05104620001178 15 N/A Serum-1 10 / Day 1 75h
15	N/A	10 / Day 1 0 75h	3075102 061	265398 109	*11 586752	1	*AAR>(200)	76	05104620001194	AA97220-01 05104620001194 15 N/A Serum-1 10 / Day 1 75h
15	N/A	11 / Day 1 1h	3524230 163	238045 662	*14 804849	1	*AAR>(200)	77	05104620001179	AA97220-01 05104620001179 15 N/A Serum-1 11 / Day 1 1h
15	N/A	11 / Day 1 1h	3390932 909	290893 227	*11 656968	1	*AAR>(200)	78	05104620001195	AA97220-01 05104620001195 15 N/A Serum-1 11 / Day 1 1h
15	N/A	12 / Day 1 1 25h	3780838 556	279060 303	*13 548464	1	*AAR>(200)	79	05104620001180	AA97220-01 05104620001180 15 N/A Serum-1 12 / Day 1 1 25h
15	N/A	12 / Day 1 1 25h	3522614 562	297967 793	*11 822132	1	*AAR>(200)	80	05104620001196	AA97220-01 05104620001196 15 N/A Serum-1 12 / Day 1 1 25h
15	N/A	13 / Day 1 1 5h	3886253 321	289824 904	*13 408970	1	*AAR>(200)	81	05104620001181	AA97220-01 05104620001181 15 N/A Serum-1 13 / Day 1 1 5h
15	N/A	13 / Day 1 1 5h	3853262 129	304153 532	*12 668806	1	*AAR>(200)	82	05104620001197	AA97220-01 05104620001197 15 N/A Serum-1 13 / Day 1 1 5h
15	N/A	14 / Day 1 2h	3527798 586	256935 97	*13 730264	1	*AAR>(200)	84	05104620001182	AA97220-01 05104620001182 15 N/A Serum-1 14 / Day 1 2h
15	N/A	14 / Day 1 2h	3868385 217	314150 47	*12 313797	1	*AAR>(200)	83	05104620001198	AA97220-01 05104620001198 15 N/A Serum-1 14 / Day 1 2h
15	N/A	15 / Day 1 2 5h	4704751 09	339816 352	*13 844981	1	*AAR>(200)	85	05104620001183	AA97220-01 05104620001183 15 N/A Serum-1 15 / Day 1 2 5h
15	N/A	15 / Day 1 2 5h	3578153 305	306388 886	*11 678470	1	*AAR>(200)	86	05104620001199	AA97220-01 05104620001199 15 N/A Serum-1 15 / Day 1 2 5h
15	N/A	16 / Day 1 3h	3996399 837	308553 716	*12 952039	1	*AAR>(200)	88	05104620001184	AA97220-01 05104620001184 15 N/A Serum-1 16 / Day 1 3h
15	N/A	16 / Day 1 3h	3585988 134	309236 289	*11 596272	1	*AAR>(200)	87	05104620001200	AA97220-01 05104620001200 15 N/A Serum-1 16 / Day 1 3h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1.00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

* - Sample Rejected

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 18
Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		0	215524 865	0 000000	-0 186		-0 186	0 0
9	0 00		0	255495 125	0 000000	-0 186			
10	1 00	1 00000	12538 393	190725 896	0 065740	0 951	-4 9		
11	2 00	0 250000	26707 777	196781 997	0 135723	2 16	8 0		
12	4 00	0 0625000	58564 459	233870 093	0 250414	4 14	3 5		
13	8 00	0 0156250	114680 508	239130 079	0 479574	8 11	1 4		
14	16 0	0 00390625	191973 656	206799 587	0 928308	15 9	-0 6		
15	40 0	0 000625000	455633 344	202294 315	2 252329	38 8	-3 0		
16	80 0	0 000156250	967972 76	213715 469	4 529259	78 1	-2 4		
17	160	0 0000390625	1649002 106	178351 712	9 245788	160	0 0		
18	200	0 0000250000	2175670 062	191034 373	11 388893	197	-1 5		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:

Slope = 0 0578282957

Intercept = 0 0107594418

R-Squared = 0 9980

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 18
Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	2514304 362	223818 879	11 233656	1	194		191		2 9
2	0 00	2782710 969	256017 545	10 869220	1	188				
3	0 00	2574391 411	221423 897	11 626529	1	201				
4	0 00	2666310 89	244727 264	10 895030	1	188				
5	0 00	2744315 482	247633 697	11 082157	1	191				
91	0 00	1352424 673	126806 307	10 665279	1	184				
92	0 00	1295216 779	118702 869	10 911419	1	189				
30	3 00	33379 808	196351 223	0 170001	1	2 75	-8 3	2 70	-10 0	2 9
63	3 00	14458 218	88322 05	0 163699	1	2 64	-12 0			
41	37 5	254507 594	124956 078	2 036776	1	35 0	-6 7	34 6	-7 7	1 6
74	37 5	195306 031	98146 033	1 989953	1	34 2	-8 8			
52	150	666118 99	81330 147	*8 190308	1	*141				
89	150	1630339 187	200877 221	8 116098	1	140	-6 7			

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)
AAR - Concentration Found is Greater than 200 (Highest Standard)

Reason for Deactivation of Sample
* UISR

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 18
Serum, Concentration of Cotinine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
15	N/A	1 / Day 1 -0 0333h	2238598 15	199049 834	11 246421	1	194	22	05104620001121	AA97220-01 05104620001121 15 N/A Serum-1 1 / Day 1 - 0333h
15	N/A	1 / Day 1 -0 0333h	2441681 996	200203 91	*12 195976	1	*AAR>(200)	20	05104620001137	AA97220-01 05104620001137 15 N/A Serum-1 1 / Day 1 - 0333h
15	N/A	1 / Day 1 -0 0333h	1910299 752	175577 865	10 880072	1	188	21	05104620001153	AA97220-01 05104620001153 15 N/A Serum-1 1 / Day 1 - 0333h
15	N/A	2 / Day 1 0h	1444582 306	125440 455	11 516080	1	199	25	05104620001122	AA97220-01 05104620001122 15 N/A Serum-1 2 / Day 1 0h
15	N/A	2 / Day 1 0h	2111495 28	189653 208	11 133454	1	192	23	05104620001138	AA97220-01 05104620001138 15 N/A Serum-1 2 / Day 1 0h
15	N/A	2 / Day 1 0h	1909575 963	175832 717	10 860186	1	188	24	05104620001154	AA97220-01 05104620001154 15 N/A Serum-1 2 / Day 1 0h
15	N/A	3 / Day 1 0 05h	1387699 791	126933 388	10 932504	1	189	27	05104620001123	AA97220-01 05104620001123 15 N/A Serum-1 3 / Day 1 05h
15	N/A	3 / Day 1 0 05h	1535739 434	138208 59	11 111751	1	192	28	05104620001139	AA97220-01 05104620001139 15 N/A Serum-1 3 / Day 1 05h
15	N/A	3 / Day 1 0 05h	1199306 606	104050 707	11 526175	1	199	26	05104620001155	AA97220-01 05104620001155 15 N/A Serum-1 3 / Day 1 05h
15	N/A	4 / Day 1 0 0833h	2432612 378	199908 002	*12 168659	1	*AAR>(200)	32	05104620001124	AA97220-01 05104620001124 15 N/A Serum-1 4 / Day 1 0833h
15	N/A	4 / Day 1 0 0833h	1968012 427	186952 016	10 526832	1	182	31	05104620001140	AA97220-01 05104620001140 15 N/A Serum-1 4 / Day 1 0833h
15	N/A	4 / Day 1 0 0833h	1883236 528	179066 479	10 516969	1	182	29	05104620001156	AA97220-01 05104620001156 15 N/A Serum-1 4 / Day 1 0833h
15	N/A	5 / Day 1 0 125h	1913400 827	166182 014	11 513886	1	199	34	05104620001125	AA97220-01 05104620001125 15 N/A Serum-1 5 / Day 1 125h
15	N/A	5 / Day 1 0 125h	1638652 977	161133 422	10 169541	1	176	33	05104620001141	AA97220-01 05104620001141 15 N/A Serum-1 5 / Day 1 125h
15	N/A	5 / Day 1 0 125h	1702685 312	164540 857	10 348100	1	179	35	05104620001157	AA97220-01 05104620001157 15 N/A Serum-1 5 / Day 1 125h
15	N/A	6 / Day 1 0 1667h	1687282 53	152062 142	11 096007	1	192	38	05104620001126	AA97220-01 05104620001126 15 N/A Serum-1 6 / Day 1 1667h
15	N/A	6 / Day 1 0 1667h	1710219 436	153930 973	11 110301	1	192	37	05104620001142	AA97220-01 05104620001142 15 N/A Serum-1 6 / Day 1 1667h
15	N/A	6 / Day 1 0 1667h	1737017 234	160180 498	10 844124	1	187	36	05104620001158	AA97220-01 05104620001158 15 N/A Serum-1 6 / Day 1 1667h
15	N/A	7 / Day 1 0 25h	1353548 024	115960 204	*11 672522	1	*AAR>(200)	42	05104620001127	AA97220-01 05104620001127 15 N/A Serum-1 7 / Day 1 25h
15	N/A	7 / Day 1 0 25h	1113648 607	103024 912	10 809508	1	187	40	05104620001143	AA97220-01 05104620001143 15 N/A Serum-1 7 / Day 1 25h
15	N/A	7 / Day 1 0 25h	1338463 875	126665 302	10 566934	1	183	39	05104620001159	AA97220-01 05104620001159 15 N/A Serum-1 7 / Day 1 25h
15	N/A	8 / Day 1 0 333h	2149304 587	175000 518	*12 281704	1	*AAR>(200)	44	05104620001128	AA97220-01 05104620001128 15 N/A Serum-1 8 / Day 1 333h
15	N/A	8 / Day 1 0 333h	1469127 253	141391 221	10 390513	1	179	45	05104620001144	AA97220-01 05104620001144 15 N/A Serum-1 8 / Day 1 333h
15	N/A	8 / Day 1 0 333h	1467053 034	127065 611	11 545634	1	199	43	05104620001160	AA97220-01 05104620001160 15 N/A Serum-1 8 / Day 1 333h
15	N/A	9 / Day 1 0 5h	1729031 708	155990 165	11 084235	1	191	48	05104620001129	AA97220-01 05104620001129 15 N/A Serum-1 9 / Day 1 5h
15	N/A	9 / Day 1 0 5h	1769741 741	169703 098	10 428459	1	180	46	05104620001145	AA97220-01 05104620001145 15 N/A Serum-1 9 / Day 1 5h
15	N/A	9 / Day 1 0 5h	1170831 879	109534 175	10 689192	1	185	47	05104620001161	AA97220-01 05104620001161 15 N/A Serum-1 9 / Day 1 5h
15	N/A	10 / Day 1 0 75h	1448926 806	123975 375	*11 687215	1	*AAR>(200)	51	05104620001130	AA97220-01 05104620001130 15 N/A Serum-1 10 / Day 1 75h
15	N/A	10 / Day 1 0 75h	1100303 234	108047 949	10 183472	1	176	50	05104620001146	AA97220-01 05104620001146 15 N/A Serum-1 10 / Day 1 75h
15	N/A	10 / Day 1 0 75h	1391276 124	120069 58	*11 587249	1	*AAR>(200)	49	05104620001162	AA97220-01 05104620001162 15 N/A Serum-1 10 / Day 1 75h
15	N/A	11 / Day 1 1h	1216448 554	101439 589	*11 991852	1	*AAR>(200)	53	05104620001131	AA97220-01 05104620001131 15 N/A Serum-1 11 / Day 1 1h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
15	N/A	11 / Day 1 1h	1325335 251	113939 848	*11 631885	1	*AAR>(200)	54	05104620001147	AA97220-01 05104620001147 15 N/A Serum-1 11 / Day 1 1h
15	N/A	11 / Day 1 1h	1139762 623	105936 942	10 758878	1	186	55	05104620001163	AA97220-01 05104620001163 15 N/A Serum-1 11 / Day 1 1h
15	N/A	12 / Day 1 1 25h	1342673 535	115083 291	*11 666972	1	*AAR>(200)	56	05104620001132	AA97220-01 05104620001132 15 N/A Serum-1 12 / Day 1 1 25h
15	N/A	12 / Day 1 1 25h	1574788 899	143716 953	10 957572	1	189	58	05104620001148	AA97220-01 05104620001148 15 N/A Serum-1 12 / Day 1 1 25h
15	N/A	12 / Day 1 1 25h	1475041 17	140060 24	10 531477	1	182	57	05104620001164	AA97220-01 05104620001164 15 N/A Serum-1 12 / Day 1 1 25h
15	N/A	13 / Day 1 1 5h	1433669 426	127978 868	11 202392	1	194	61	05104620001133	AA97220-01 05104620001133 15 N/A Serum-1 13 / Day 1 1 5h
15	N/A	13 / Day 1 1 5h	1254960 893	122142 92	10 274528	1	177	59	05104620001149	AA97220-01 05104620001149 15 N/A Serum-1 13 / Day 1 1 5h
15	N/A	13 / Day 1 1 5h	1527842 551	146814 716	10 406604	1	180	60	05104620001165	AA97220-01 05104620001165 15 N/A Serum-1 13 / Day 1 1 5h
15	N/A	14 / Day 1 2h	1097760 102	90226 567	*12 166706	1	*AAR>(200)	64	05104620001134	AA97220-01 05104620001134 15 N/A Serum-1 14 / Day 1 2h
15	N/A	14 / Day 1 2h	998023 358	98651	10 116708	1	175	65	05104620001150	AA97220-01 05104620001150 15 N/A Serum-1 14 / Day 1 2h
15	N/A	14 / Day 1 2h	842449 564	85432 255	*9 861025	1	*170	62	05104620001166	AA97220-01 05104620001166 15 N/A Serum-1 14 / Day 1 2h
15	N/A	15 / Day 1 2 5h	1627126 965	148644 262	10 946450	1	189	67	05104620001135	AA97220-01 05104620001135 15 N/A Serum-1 15 / Day 1 2 5h
15	N/A	15 / Day 1 2 5h	915530 447	94900 503	9 647267	1	167	66	05104620001151	AA97220-01 05104620001151 15 N/A Serum-1 15 / Day 1 2 5h
15	N/A	15 / Day 1 2 5h	1910356 931	187919 677	10 165816	1	176	68	05104620001167	AA97220-01 05104620001167 15 N/A Serum-1 15 / Day 1 2 5h
15	N/A	16 / Day 1 3h	2015890 446	174962 418	11 521848	1	199	70	05104620001136	AA97220-01 05104620001136 15 N/A Serum-1 16 / Day 1 3h
15	N/A	16 / Day 1 3h	1208854 934	126927 643	9 523969	1	165	71	05104620001152	AA97220-01 05104620001152 15 N/A Serum-1 16 / Day 1 3h
15	N/A	16 / Day 1 3h	1783674 029	179492 762	9 937303	1	172	69	05104620001168	AA97220-01 05104620001168 15 N/A Serum-1 16 / Day 1 3h
16	N/A	1 / Day 1 -0 0333h	935037 481	99142 685	9 431230	1	163	72	05104620001265	AA97220-01 05104620001265 16 N/A Serum-1 1 / Day 1 - 0333h
16	N/A	2 / Day 1 0h	1018960 477	100666 002	10 122191	1	175	73	05104620001266	AA97220-01 05104620001266 16 N/A Serum-1 2 / Day 1 0h
16	N/A	3 / Day 1 0 05h	766267 403	74901 706	*10 230306	1	*177	75	05104620001267	AA97220-01 05104620001267 16 N/A Serum-1 3 / Day 1 05h
16	N/A	4 / Day 1 0 0833h	997429 081	96927 581	10 290457	1	178	76	05104620001268	AA97220-01 05104620001268 16 N/A Serum-1 4 / Day 1 0833h
16	N/A	5 / Day 1 0 125h	1022142 382	97166 682	10 519474	1	182	77	05104620001269	AA97220-01 05104620001269 16 N/A Serum-1 5 / Day 1 125h
16	N/A	6 / Day 1 0 1667h	949642 414	89680 367	10 589190	1	183	78	05104620001270	AA97220-01 05104620001270 16 N/A Serum-1 6 / Day 1 1667h
16	N/A	7 / Day 1 0 25h	971424 667	94444 38	10 285680	1	178	79	05104620001271	AA97220-01 05104620001271 16 N/A Serum-1 7 / Day 1 25h
16	N/A	8 / Day 1 0 333h	1057974 182	105216 355	10 055226	1	174	80	05104620001272	AA97220-01 05104620001272 16 N/A Serum-1 8 / Day 1 333h
16	N/A	9 / Day 1 0 5h	881115 643	84571 61	*10 418575	1	*180	81	05104620001273	AA97220-01 05104620001273 16 N/A Serum-1 9 / Day 1 5h
16	N/A	10 / Day 1 0 75h	1076809 335	103597 779	10 394135	1	180	82	05104620001274	AA97220-01 05104620001274 16 N/A Serum-1 10 / Day 1 75h
16	N/A	11 / Day 1 1h	1219932 826	110542 85	11 035837	1	191	83	05104620001275	AA97220-01 05104620001275 16 N/A Serum-1 11 / Day 1 1h
16	N/A	12 / Day 1 1 25h	1163754 013	107763 606	10 799138	1	187	84	05104620001276	AA97220-01 05104620001276 16 N/A Serum-1 12 / Day 1 1 25h
16	N/A	13 / Day 1 1 5h	1232211 339	106248 435	*11 597454	1	*AAR>(200)	85	05104620001277	AA97220-01 05104620001277 16 N/A Serum-1 13 / Day 1 1 5h
16	N/A	14 / Day 1 2h	1085268 06	106695 512	10 171637	1	176	86	05104620001278	AA97220-01 05104620001278 16 N/A Serum-1 14 / Day 1 2h
16	N/A	15 / Day 1 2 5h	1475986 916	136719 334	10 795744	1	187	87	05104620001279	AA97220-01 05104620001279 16 N/A Serum-1 15 / Day 1 2 5h
16	N/A	16 / Day 1 3h	1815102 494	183942 934	9 867748	1	170	88	05104620001280	AA97220-01 05104620001280 16 N/A Serum-1 16 / Day 1 3h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1.00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

* - Sample Rejected

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 19
Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		0	3436539 007	0 000000	-0 195		-0 195	0 0
9	0 00		0	3198497 835	0 000000	-0 195			
10	1 00	1 00000	26084 787	2899190 327	0 008997	0 975	-2 5		
11	2 00	0 250000	61466 588	3482970 747	0 017648	2 10	5 0		
12	4 00	0 0625000	109006 208	3339791 564	0 032639	4 05	1 3		
13	8 00	0 0156250	212526 82	3364716 148	0 063163	8 02	0 3		
14	16 0	0 00390625	406636 514	3390545 737	0 119932	15 4	-3 8		
15	40 0	0 000625000	1007083 413	3319550 528	0 303379	39 2	-2 0		
16	80 0	0 000156250	1798332 397	2953556 694	0 608870	78 9	-1 4		
17	160	0 0000390625	3941033 658	3216012 478	1 225441	159	-0 6		
18	200	0 0000250000	4834691 028	3025659 646	1 597897	207	3 5		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:

Slope = 0 00769353939

Intercept = 0 00149722429

R-Squared = 0 9989

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 19
Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	5000266 007	3222297 268	1 551771	1	202		200		1 0
2	0 00	4665153 58	3028803 032	1 540263	1	200				
3	0 00	4828614 195	3185968 343	1 515588	1	197				
4	0 00	4994776 76	3238232 952	1 542439	1	200				
5	0 00	4860563 885	3205602 721	1 516271	1	197				
91	0 00	4920451 239	3179710 833	1 547452	1	201				
92	0 00	4719922 649	3061955 968	1 541473	1	200				
30	3 00	63959 713	2743634 922	0 023312	1	2 84	-5 3	2 83	-5 7	0 5
63	3 00	75240 663	3245207 247	0 023185	1	2 82	-6 0			
41	37 5	842042 528	2963298 569	0 284157	1	36 7	-2 1	36 2	-3 5	2 1
74	37 5	931873 636	3386764 972	0 275152	1	35 6	-5 1			
52	150	3310265 184	2912890 649	1 136419	1	148	-1 3	146	-2 7	1 9
89	150	3432613 262	3091853 988	1 110212	1	144	-4 0			

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)
AAR - Concentration Found is Greater than 200 (Highest Standard)

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 19
Serum, Concentration of Cotinine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
16	N/A	1 / Day 1 -0 0333h	5390604 743	3211375 979	*1 678597	1	*AAR>(200)	23	05104620001201	AA97220-01 05104620001201 16 N/A Serum-1 1 / Day 1 - 0333h
16	N/A	1 / Day 1 -0 0333h	4840364 156	3463126 557	1 397686	1	181	21	05104620001217	AA97220-01 05104620001217 16 N/A Serum-1 1 / Day 1 - 0333h
16	N/A	1 / Day 1 -0 0333h	4022115 133	3227285 331	1 246284	1	162	20	05104620001233	AA97220-01 05104620001233 16 N/A Serum-1 1 / Day 1 - 0333h
16	N/A	1 / Day 1 -0 0333h	4752957 446	3402307 664	1 396980	1	181	22	05104620001249	AA97220-01 05104620001249 16 N/A Serum-1 1 / Day 1 - 0333h
16	N/A	2 / Day 1 0h	3904891 612	2327123 297	*1 677991	1	*AAR>(200)	26	05104620001202	AA97220-01 05104620001202 16 N/A Serum-1 2 / Day 1 0h
16	N/A	2 / Day 1 0h	4824735 656	3543752 688	1 361476	1	177	27	05104620001218	AA97220-01 05104620001218 16 N/A Serum-1 2 / Day 1 0h
16	N/A	2 / Day 1 0h	4106360 877	3248600 697	1 264040	1	164	25	05104620001234	AA97220-01 05104620001234 16 N/A Serum-1 2 / Day 1 0h
16	N/A	2 / Day 1 0h	4874023 952	3489547 312	1 396750	1	181	24	05104620001250	AA97220-01 05104620001250 16 N/A Serum-1 2 / Day 1 0h
16	N/A	3 / Day 1 0 05h	5853728 71	3519642 233	*1 663160	1	*AAR>(200)	28	05104620001203	AA97220-01 05104620001203 16 N/A Serum-1 3 / Day 1 05h
16	N/A	3 / Day 1 0 05h	4423956 31	3197702 749	1 383480	1	180	31	05104620001219	AA97220-01 05104620001219 16 N/A Serum-1 3 / Day 1 05h
16	N/A	3 / Day 1 0 05h	3882266 396	3108698 483	1 248840	1	162	29	05104620001235	AA97220-01 05104620001235 16 N/A Serum-1 3 / Day 1 05h
16	N/A	3 / Day 1 0 05h	4309751 097	3134332 801	1 375014	1	179	32	05104620001251	AA97220-01 05104620001251 16 N/A Serum-1 3 / Day 1 05h
16	N/A	4 / Day 1 0 0833h	5074204 289	2990902 154	*1 696546	1	*AAR>(200)	34	05104620001204	AA97220-01 05104620001204 16 N/A Serum-1 4 / Day 1 0833h
16	N/A	4 / Day 1 0 0833h	4769112 062	3454542 554	1 380534	1	179	35	05104620001220	AA97220-01 05104620001220 16 N/A Serum-1 4 / Day 1 0833h
16	N/A	4 / Day 1 0 0833h	3385236 762	2781442 612	1 217079	1	158	33	05104620001236	AA97220-01 05104620001236 16 N/A Serum-1 4 / Day 1 0833h
16	N/A	4 / Day 1 0 0833h	4397270 527	3174862 973	1 385027	1	180	36	05104620001252	AA97220-01 05104620001252 16 N/A Serum-1 4 / Day 1 0833h
16	N/A	5 / Day 1 0 125h	4348415 455	2587715 274	*1 680407	1	*AAR>(200)	38	05104620001205	AA97220-01 05104620001205 16 N/A Serum-1 5 / Day 1 125h
16	N/A	5 / Day 1 0 125h	3793533 863	2816499 076	1 346897	1	175	40	05104620001221	AA97220-01 05104620001221 16 N/A Serum-1 5 / Day 1 125h
16	N/A	5 / Day 1 0 125h	3275293 79	2691734 518	1 216797	1	158	39	05104620001237	AA97220-01 05104620001237 16 N/A Serum-1 5 / Day 1 125h
16	N/A	5 / Day 1 0 125h	3675886 526	2667598 281	1 377976	1	179	37	05104620001253	AA97220-01 05104620001253 16 N/A Serum-1 5 / Day 1 125h
16	N/A	6 / Day 1 0 1667h	5071010 783	3094816 909	*1 638550	1	*AAR>(200)	45	05104620001206	AA97220-01 05104620001206 16 N/A Serum-1 6 / Day 1 1667h
16	N/A	6 / Day 1 0 1667h	3706332 156	2674575 952	1 385764	1	180	44	05104620001222	AA97220-01 05104620001222 16 N/A Serum-1 6 / Day 1 1667h
16	N/A	6 / Day 1 0 1667h	3645820 611	2934961 362	1 242204	1	161	43	05104620001238	AA97220-01 05104620001238 16 N/A Serum-1 6 / Day 1 1667h
16	N/A	6 / Day 1 0 1667h	3746267 442	2724709 889	1 374923	1	179	42	05104620001254	AA97220-01 05104620001254 16 N/A Serum-1 6 / Day 1 1667h
16	N/A	7 / Day 1 0 25h	4801704 15	2946449 707	*1 629658	1	*AAR>(200)	47	05104620001207	AA97220-01 05104620001207 16 N/A Serum-1 7 / Day 1 25h
16	N/A	7 / Day 1 0 25h	4398781 896	3084389 8	1 426143	1	185	48	05104620001223	AA97220-01 05104620001223 16 N/A Serum-1 7 / Day 1 25h
16	N/A	7 / Day 1 0 25h	4043291 453	3151387 827	1 283019	1	167	46	05104620001239	AA97220-01 05104620001239 16 N/A Serum-1 7 / Day 1 25h
16	N/A	7 / Day 1 0 25h	4169689 089	2951155 262	1 412901	1	183	49	05104620001255	AA97220-01 05104620001255 16 N/A Serum-1 7 / Day 1 25h
16	N/A	8 / Day 1 0 333h	4465979 599	2771084 262	*1 611636	1	*AAR>(200)	53	05104620001208	AA97220-01 05104620001208 16 N/A Serum-1 8 / Day 1 333h
16	N/A	8 / Day 1 0 333h	4432560 71	3091422 243	1 433826	1	186	51	05104620001224	AA97220-01 05104620001224 16 N/A Serum-1 8 / Day 1 333h
16	N/A	8 / Day 1 0 333h	3560234 9	2715280 409	1 311185	1	170	54	05104620001240	AA97220-01 05104620001240 16 N/A Serum-1 8 / Day 1 333h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
16	N/A	8 / Day 1 0 333h	4153971 797	2944639 803	1 410689	1	183	50	05104620001256	AA97220-01 05104620001256 16 N/A Serum-1 8 / Day 1 333h
16	N/A	9 / Day 1 0 5h	5015406 818	2984953 682	*1 680229	1	*AAR>(200)	58	05104620001209	AA97220-01 05104620001209 16 N/A Serum-1 9 / Day 1 5h
16	N/A	9 / Day 1 0 5h	4060226 555	2658148 901	1 527464	1	198	55	05104620001225	AA97220-01 05104620001225 16 N/A Serum-1 9 / Day 1 5h
16	N/A	9 / Day 1 0 5h	3716787 723	2788510 924	1 332893	1	173	56	05104620001241	AA97220-01 05104620001241 16 N/A Serum-1 9 / Day 1 5h
16	N/A	9 / Day 1 0 5h	3631278 483	2586386 63	1 403997	1	182	57	05104620001257	AA97220-01 05104620001257 16 N/A Serum-1 9 / Day 1 5h
16	N/A	10 / Day 1 0 75h	5171632 009	3007779 273	*1 719419	1	*AAR>(200)	62	05104620001210	AA97220-01 05104620001210 16 N/A Serum-1 10 / Day 1 75h
16	N/A	10 / Day 1 0 75h	4593002 256	3224537 186	1 424391	1	185	60	05104620001226	AA97220-01 05104620001226 16 N/A Serum-1 10 / Day 1 75h
16	N/A	10 / Day 1 0 75h	4326342 249	3342601 385	1 294304	1	168	61	05104620001242	AA97220-01 05104620001242 16 N/A Serum-1 10 / Day 1 75h
16	N/A	10 / Day 1 0 75h	4060935 279	2865948 425	1 416960	1	184	59	05104620001258	AA97220-01 05104620001258 16 N/A Serum-1 10 / Day 1 75h
16	N/A	11 / Day 1 1h	5417290 814	3114648 112	*1 739295	1	*AAR>(200)	66	05104620001211	AA97220-01 05104620001211 16 N/A Serum-1 11 / Day 1 1h
16	N/A	11 / Day 1 1h	4571066 247	3302269 22	1 384220	1	180	64	05104620001227	AA97220-01 05104620001227 16 N/A Serum-1 11 / Day 1 1h
16	N/A	11 / Day 1 1h	4208147 723	3412008 935	1 233334	1	160	65	05104620001243	AA97220-01 05104620001243 16 N/A Serum-1 11 / Day 1 1h
16	N/A	11 / Day 1 1h	4610946 4	3390667 642	1 359893	1	177	67	05104620001259	AA97220-01 05104620001259 16 N/A Serum-1 11 / Day 1 1h
16	N/A	12 / Day 1 1 25h	5059316 626	2957365 944	*1 710751	1	*AAR>(200)	71	05104620001212	AA97220-01 05104620001212 16 N/A Serum-1 12 / Day 1 1 25h
16	N/A	12 / Day 1 1 25h	4565416 887	3365137 795	1 356681	1	176	68	05104620001228	AA97220-01 05104620001228 16 N/A Serum-1 12 / Day 1 1 25h
16	N/A	12 / Day 1 1 25h	3484788 93	3053312 539	1 141314	1	148	69	05104620001244	AA97220-01 05104620001244 16 N/A Serum-1 12 / Day 1 1 25h
16	N/A	12 / Day 1 1 25h	4036560 229	2873720 07	1 404646	1	182	70	05104620001260	AA97220-01 05104620001260 16 N/A Serum-1 12 / Day 1 1 25h
16	N/A	13 / Day 1 1 5h	4988335 527	3051165 057	*1 634895	1	*AAR>(200)	76	05104620001213	AA97220-01 05104620001213 16 N/A Serum-1 13 / Day 1 1 5h
16	N/A	13 / Day 1 1 5h	4025069 737	2984071 1	1 348852	1	175	72	05104620001229	AA97220-01 05104620001229 16 N/A Serum-1 13 / Day 1 1 5h
16	N/A	13 / Day 1 1 5h	3896597 902	3254059 838	1 197457	1	155	73	05104620001245	AA97220-01 05104620001245 16 N/A Serum-1 13 / Day 1 1 5h
16	N/A	13 / Day 1 1 5h	4363441 749	3441836 928	1 267765	1	165	75	05104620001261	AA97220-01 05104620001261 16 N/A Serum-1 13 / Day 1 1 5h
16	N/A	14 / Day 1 2h	5507538 834	3239364 784	*1 700191	1	*AAR>(200)	79	05104620001214	AA97220-01 05104620001214 16 N/A Serum-1 14 / Day 1 2h
16	N/A	14 / Day 1 2h	4205375 287	3278865 544	1 282570	1	167	77	05104620001230	AA97220-01 05104620001230 16 N/A Serum-1 14 / Day 1 2h
16	N/A	14 / Day 1 2h	3734905 479	3218556 372	1 160429	1	151	80	05104620001246	AA97220-01 05104620001246 16 N/A Serum-1 14 / Day 1 2h
16	N/A	14 / Day 1 2h	4153355 56	3190866 378	1 301639	1	169	78	05104620001262	AA97220-01 05104620001262 16 N/A Serum-1 14 / Day 1 2h
16	N/A	15 / Day 1 2 5h	5214333 391	3217556 955	*1 620588	1	*AAR>(200)	81	05104620001215	AA97220-01 05104620001215 16 N/A Serum-1 15 / Day 1 2 5h
16	N/A	15 / Day 1 2 5h	3709569 646	2932240 314	1 265097	1	164	84	05104620001231	AA97220-01 05104620001231 16 N/A Serum-1 15 / Day 1 2 5h
16	N/A	15 / Day 1 2 5h	3440745 018	3150398 278	1 092162	1	142	83	05104620001247	AA97220-01 05104620001247 16 N/A Serum-1 15 / Day 1 2 5h
16	N/A	15 / Day 1 2 5h	4413351 077	3315997 875	1 330927	1	173	82	05104620001263	AA97220-01 05104620001263 16 N/A Serum-1 15 / Day 1 2 5h
16	N/A	16 / Day 1 3h	4438520 401	3297236 414	1 346134	1	175	87	05104620001216	AA97220-01 05104620001216 16 N/A Serum-1 16 / Day 1 3h
16	N/A	16 / Day 1 3h	4103333 693	3291116 71	1 246791	1	162	85	05104620001232	AA97220-01 05104620001232 16 N/A Serum-1 16 / Day 1 3h
16	N/A	16 / Day 1 3h	3395963 927	2999791 11	1 132067	1	147	86	05104620001248	AA97220-01 05104620001248 16 N/A Serum-1 16 / Day 1 3h
16	N/A	16 / Day 1 3h	3835626 334	3040690 476	1 261433	1	164	88	05104620001264	AA97220-01 05104620001264 16 N/A Serum-1 16 / Day 1 3h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1.00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

* - Sample Rejected

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 20
Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		0	2631611 566	0 000000	-0 0668		0 000200	47400 0
9	0 00		3184 286	3060665 916	0 001040	0 0672			
10	1 00	1 00000	28104 415	3467034 628	0 008106	0 978	-2 2		
11	2 00	0 250000	65929 445	3897169 765	0 016917	2 11	5 5		
12	4 00	0 0625000	107130 428	3522765 622	0 030411	3 85	-3 8		
13	8 00	0 0156250	216394 603	3317025 823	0 065238	8 34	4 3		
14	16 0	0 00390625	367511 267	3043276 284	0 120762	15 5	-3 1		
15	40 0	0 000625000	876550 554	2855394 096	0 306981	39 5	-1 3		
16	80 0	0 000156250	1796214 337	2910771 806	0 617092	79 5	-0 6		
17	160	0 0000390625	3553834 521	2874156 733	1 236479	159	-0 6		
18	200	0 0000250000	4063115 984	2578989 301	1 575468	203	1 5		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:

Slope = 0 00775923455

Intercept = 0 000518576596

R-Squared = 0 9986

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 20
Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	5316156 748	3493681 018	1 521649	1	196		196		0 8
2	0 00	5639130 994	3666188 836	1 538145	1	198				
3	0 00	6405077 144	4193189 458	1 527495	1	197				
4	0 00	6058287 64	3991162 934	1 517925	1	196				
5	0 00	6399899 758	4265868 183	1 500257	1	193				
91	0 00	4578911 853	3016212 231	1 518100	1	196				
92	0 00	4973684 1	3248002 111	1 531306	1	197				
30	3 00	94768 735	4311359 156	0 021981	1	2 77	-7 7	2 82	-6 0	2 3
63	3 00	80488 059	3549583 084	0 022675	1	2 86	-4 7			
41	37 5	723417 343	2620485 309	0 276062	1	35 5	-5 3	35 9	-4 3	1 6
74	37 5	951483 178	3367927 662	0 282513	1	36 3	-3 2			
52	150	3916615 201	3500783 006	1 118783	1	144	-4 0	142	-5 3	2 5
89	150	3650877 598	3387694 503	1 077688	1	139	-7 3			

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)
AAR - Concentration Found is Greater than 200 (Highest Standard)

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 20
Serum, Concentration of Cotinine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
17	N/A	1 / Day 1 -0 0333h	7550768 57	3751984 832	*2 012473	1	*AAR>(200)	23	05104620001297	AA97220-01 05104620001297 17 N/A Serum-1 1 / Day 1 - 0333h
17	N/A	1 / Day 1 -0 0333h	6774502 999	3711444 909	*1 825301	1	*AAR>(200)	21	05104620001313	AA97220-01 05104620001313 17 N/A Serum-1 1 / Day 1 - 0333h
17	N/A	1 / Day 1 -0 0333h	4548456 484	3436094 668	1 323729	1	171	22	05104620001329	AA97220-01 05104620001329 17 N/A Serum-1 1 / Day 1 - 0333h
17	N/A	1 / Day 1 -0 0333h	5515532 259	3444682 16	*1 601173	1	*AAR>(200)	20	05104620001345	AA97220-01 05104620001345 17 N/A Serum-1 1 / Day 1 - 0333h
17	N/A	2 / Day 1 0h	6927411 121	3566001 238	*1 942627	1	*AAR>(200)	24	05104620001298	AA97220-01 05104620001298 17 N/A Serum-1 2 / Day 1 0h
17	N/A	2 / Day 1 0h	6730313 808	3813858 239	*1 764700	1	*AAR>(200)	27	05104620001314	AA97220-01 05104620001314 17 N/A Serum-1 2 / Day 1 0h
17	N/A	2 / Day 1 0h	4783872 742	3658830 286	1 307487	1	168	26	05104620001330	AA97220-01 05104620001330 17 N/A Serum-1 2 / Day 1 0h
17	N/A	2 / Day 1 0h	6108604 348	3769757 603	*1 620424	1	*AAR>(200)	25	05104620001346	AA97220-01 05104620001346 17 N/A Serum-1 2 / Day 1 0h
17	N/A	3 / Day 1 0 05h	7046611 018	3638883 576	*1 936476	1	*AAR>(200)	31	05104620001299	AA97220-01 05104620001299 17 N/A Serum-1 3 / Day 1 05h
17	N/A	3 / Day 1 0 05h	7088621 787	3874253 24	*1 829674	1	*AAR>(200)	29	05104620001315	AA97220-01 05104620001315 17 N/A Serum-1 3 / Day 1 05h
17	N/A	3 / Day 1 0 05h	4905870 324	3731327 492	1 314779	1	169	28	05104620001331	AA97220-01 05104620001331 17 N/A Serum-1 3 / Day 1 05h
17	N/A	3 / Day 1 0 05h	5369100 338	3334947 584	*1 609950	1	*AAR>(200)	32	05104620001347	AA97220-01 05104620001347 17 N/A Serum-1 3 / Day 1 05h
17	N/A	4 / Day 1 0 0833h	6283941 828	3147201 591	*1 996676	1	*AAR>(200)	36	05104620001300	AA97220-01 05104620001300 17 N/A Serum-1 4 / Day 1 0833h
17	N/A	4 / Day 1 0 0833h	7089616 147	3786161 276	*1 872508	1	*AAR>(200)	34	05104620001316	AA97220-01 05104620001316 17 N/A Serum-1 4 / Day 1 0833h
17	N/A	4 / Day 1 0 0833h	4152686 174	3266645 037	1 271239	1	164	33	05104620001332	AA97220-01 05104620001332 17 N/A Serum-1 4 / Day 1 0833h
17	N/A	4 / Day 1 0 0833h	5439939 877	3319690 809	*1 638689	1	*AAR>(200)	35	05104620001348	AA97220-01 05104620001348 17 N/A Serum-1 4 / Day 1 0833h
17	N/A	5 / Day 1 0 125h	5577047 582	2743219 817	*2 033030	1	*AAR>(200)	40	05104620001301	AA97220-01 05104620001301 17 N/A Serum-1 5 / Day 1 125h
17	N/A	5 / Day 1 0 125h	5426223 488	2933224 875	*1 849917	1	*AAR>(200)	39	05104620001317	AA97220-01 05104620001317 17 N/A Serum-1 5 / Day 1 125h
17	N/A	5 / Day 1 0 125h	4469816 228	3641980 732	1 227304	1	158	37	05104620001333	AA97220-01 05104620001333 17 N/A Serum-1 5 / Day 1 125h
17	N/A	5 / Day 1 0 125h	5157244 672	3193012 147	*1 615166	1	*AAR>(200)	38	05104620001349	AA97220-01 05104620001349 17 N/A Serum-1 5 / Day 1 125h
17	N/A	6 / Day 1 0 1667h	6162227 262	3220852 244	*1 913229	1	*AAR>(200)	45	05104620001302	AA97220-01 05104620001302 17 N/A Serum-1 6 / Day 1 1667h
17	N/A	6 / Day 1 0 1667h	6162223 859	3477546 651	*1 772003	1	*AAR>(200)	44	05104620001318	AA97220-01 05104620001318 17 N/A Serum-1 6 / Day 1 1667h
17	N/A	6 / Day 1 0 1667h	4792560 128	3894639 286	1 230553	1	159	43	05104620001334	AA97220-01 05104620001334 17 N/A Serum-1 6 / Day 1 1667h
17	N/A	6 / Day 1 0 1667h	5532146 212	3445693 954	*1 605525	1	*AAR>(200)	42	05104620001350	AA97220-01 05104620001350 17 N/A Serum-1 6 / Day 1 1667h
17	N/A	7 / Day 1 0 25h	6435421 598	3212851 698	*2 003025	1	*AAR>(200)	48	05104620001303	AA97220-01 05104620001303 17 N/A Serum-1 7 / Day 1 25h
17	N/A	7 / Day 1 0 25h	6456979 43	3563230 159	*1 812114	1	*AAR>(200)	49	05104620001319	AA97220-01 05104620001319 17 N/A Serum-1 7 / Day 1 25h
17	N/A	7 / Day 1 0 25h	4622545 674	3780537 177	1 222722	1	158	46	05104620001335	AA97220-01 05104620001335 17 N/A Serum-1 7 / Day 1 25h
17	N/A	7 / Day 1 0 25h	6402306 35	3859895 747	*1 658673	1	*AAR>(200)	47	05104620001351	AA97220-01 05104620001351 17 N/A Serum-1 7 / Day 1 25h
17	N/A	8 / Day 1 0 333h	5887026 025	2960947 102	*1 988224	1	*AAR>(200)	50	05104620001304	AA97220-01 05104620001304 17 N/A Serum-1 8 / Day 1 333h
17	N/A	8 / Day 1 0 333h	6433435 626	3569988 447	*1 802089	1	*AAR>(200)	54	05104620001320	AA97220-01 05104620001320 17 N/A Serum-1 8 / Day 1 333h
17	N/A	8 / Day 1 0 333h	4329625 512	3551069 609	1 219245	1	157	51	05104620001336	AA97220-01 05104620001336 17 N/A Serum-1 8 / Day 1 333h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
17	N/A	8 / Day 1 0 333h	6285994 272	3735715 644	*1 682675	1	*AAR>(200)	53	05104620001352	AA97220-01 05104620001352 17 N/A Serum-1 8 / Day 1 333h
17	N/A	9 / Day 1 0 5h	6805757 802	3502679 273	*1 943015	1	*AAR>(200)	58	05104620001305	AA97220-01 05104620001305 17 N/A Serum-1 9 / Day 1 5h
17	N/A	9 / Day 1 0 5h	6318998 785	3517947 519	*1 796217	1	*AAR>(200)	55	05104620001321	AA97220-01 05104620001321 17 N/A Serum-1 9 / Day 1 5h
17	N/A	9 / Day 1 0 5h	4173832 734	3309789 737	1 261057	1	162	56	05104620001337	AA97220-01 05104620001337 17 N/A Serum-1 9 / Day 1 5h
17	N/A	9 / Day 1 0 5h	6563153 422	3857877 557	*1 701234	1	*AAR>(200)	57	05104620001353	AA97220-01 05104620001353 17 N/A Serum-1 9 / Day 1 5h
17	N/A	10 / Day 1 0 75h	7347984 713	3851523 796	*1 907812	1	*AAR>(200)	60	05104620001306	AA97220-01 05104620001306 17 N/A Serum-1 10 / Day 1 75h
17	N/A	10 / Day 1 0 75h	6894551 894	3672990 111	*1 877095	1	*AAR>(200)	61	05104620001322	AA97220-01 05104620001322 17 N/A Serum-1 10 / Day 1 75h
17	N/A	10 / Day 1 0 75h	4319319 266	3368492 143	1 282271	1	165	62	05104620001338	AA97220-01 05104620001338 17 N/A Serum-1 10 / Day 1 75h
17	N/A	10 / Day 1 0 75h	6052927 292	3582025 117	*1 689806	1	*AAR>(200)	59	05104620001354	AA97220-01 05104620001354 17 N/A Serum-1 10 / Day 1 75h
17	N/A	11 / Day 1 1h	5783044 819	3062988 235	*1 888040	1	*AAR>(200)	64	05104620001307	AA97220-01 05104620001307 17 N/A Serum-1 11 / Day 1 1h
17	N/A	11 / Day 1 1h	4954926 784	2839733 653	*1 744856	1	*AAR>(200)	66	05104620001323	AA97220-01 05104620001323 17 N/A Serum-1 11 / Day 1 1h
17	N/A	11 / Day 1 1h	4579709 852	3635129 377	1 259848	1	162	65	05104620001339	AA97220-01 05104620001339 17 N/A Serum-1 11 / Day 1 1h
17	N/A	11 / Day 1 1h	5958955 918	3687399 626	*1 616032	1	*AAR>(200)	67	05104620001355	AA97220-01 05104620001355 17 N/A Serum-1 11 / Day 1 1h
17	N/A	12 / Day 1 1 25h	6366756 302	3527196 288	*1 805047	1	*AAR>(200)	68	05104620001308	AA97220-01 05104620001308 17 N/A Serum-1 12 / Day 1 1 25h
17	N/A	12 / Day 1 1 25h	5976367 08	3426944 626	*1 743935	1	*AAR>(200)	71	05104620001324	AA97220-01 05104620001324 17 N/A Serum-1 12 / Day 1 1 25h
17	N/A	12 / Day 1 1 25h	4426459 044	3517091 1	1 258557	1	162	70	05104620001340	AA97220-01 05104620001340 17 N/A Serum-1 12 / Day 1 1 25h
17	N/A	12 / Day 1 1 25h	6421402 032	3818306 914	*1 681741	1	*AAR>(200)	69	05104620001356	AA97220-01 05104620001356 17 N/A Serum-1 12 / Day 1 1 25h
17	N/A	13 / Day 1 1 5h	6587707 422	3633395 362	*1 813100	1	*AAR>(200)	73	05104620001309	AA97220-01 05104620001309 17 N/A Serum-1 13 / Day 1 1 5h
17	N/A	13 / Day 1 1 5h	5810371 155	3408298 797	*1 704772	1	*AAR>(200)	75	05104620001325	AA97220-01 05104620001325 17 N/A Serum-1 13 / Day 1 1 5h
17	N/A	13 / Day 1 1 5h	3826126 448	3089375 323	1 238479	1	160	76	05104620001341	AA97220-01 05104620001341 17 N/A Serum-1 13 / Day 1 1 5h
17	N/A	13 / Day 1 1 5h	5298233 676	3216890 632	*1 647005	1	*AAR>(200)	72	05104620001357	AA97220-01 05104620001357 17 N/A Serum-1 13 / Day 1 1 5h
17	N/A	14 / Day 1 2h	5704416 791	3101937 384	*1 838985	1	*AAR>(200)	78	05104620001310	AA97220-01 05104620001310 17 N/A Serum-1 14 / Day 1 2h
17	N/A	14 / Day 1 2h	5580437 115	3455165 867	*1 615100	1	*AAR>(200)	77	05104620001326	AA97220-01 05104620001326 17 N/A Serum-1 14 / Day 1 2h
17	N/A	14 / Day 1 2h	4076861 335	3357246 19	1 214347	1	156	80	05104620001342	AA97220-01 05104620001342 17 N/A Serum-1 14 / Day 1 2h
17	N/A	14 / Day 1 2h	5186296 056	3175982 069	*1 632974	1	*AAR>(200)	79	05104620001358	AA97220-01 05104620001358 17 N/A Serum-1 14 / Day 1 2h
17	N/A	15 / Day 1 2 5h	5500944 545	3162204 109	*1 739592	1	*AAR>(200)	83	05104620001311	AA97220-01 05104620001311 17 N/A Serum-1 15 / Day 1 2 5h
17	N/A	15 / Day 1 2 5h	5251599 205	3134579 591	*1 675376	1	*AAR>(200)	82	05104620001327	AA97220-01 05104620001327 17 N/A Serum-1 15 / Day 1 2 5h
17	N/A	15 / Day 1 2 5h	3968520 752	3418265 898	1 160975	1	150	84	05104620001343	AA97220-01 05104620001343 17 N/A Serum-1 15 / Day 1 2 5h
17	N/A	15 / Day 1 2 5h	5225403 767	3247174 822	*1 609215	1	*AAR>(200)	81	05104620001359	AA97220-01 05104620001359 17 N/A Serum-1 15 / Day 1 2 5h
17	N/A	16 / Day 1 3h	6123914 542	3637541 318	*1 683531	1	*AAR>(200)	86	05104620001312	AA97220-01 05104620001312 17 N/A Serum-1 16 / Day 1 3h
17	N/A	16 / Day 1 3h	5355449 754	3384504 805	*1 582344	1	*AAR>(200)	85	05104620001328	AA97220-01 05104620001328 17 N/A Serum-1 16 / Day 1 3h
17	N/A	16 / Day 1 3h	3121702 87	2632516 351	1 185825	1	153	88	05104620001344	AA97220-01 05104620001344 17 N/A Serum-1 16 / Day 1 3h
17	N/A	16 / Day 1 3h	5845189 934	3754942 85	*1 556665	1	*AAR>(200)	87	05104620001360	AA97220-01 05104620001360 17 N/A Serum-1 16 / Day 1 3h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1.00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

* - Sample Rejected

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 22
 Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		2981 333	479928 095	0 006212	0 0196		0 00541	371 5
9	0 00		2312 703	489800 506	0 004722	-0 00879			
10	1 00	1 00000	27815 002	490288 794	0 056732	0 982	-1 8		
11	2 00	0 250000	55167 35	495748 482	0 111281	2 02	1 0		
12	4 00	0 0625000	120488 108	531806 156	0 226564	4 22	5 5		
13	8 00	0 0156250	219889 932	512828 28	0 428779	8 07	0 9		
14	16 0	0 00390625	499947 408	595634 613	0 839353	15 9	-0 6		
15	40 0	0 000625000	1137172 805	550829 767	2 064472	39 2	-2 0		
16	80 0	0 000156250	2250235 686	541674 902	4 154218	79 0	-1 3		
17	160	0 0000390625	4262204 003	505249 141	8 435846	161	0 6		
18	200	0 0000250000	5101706 272	494356 871	10 319885	196	-2 0		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:

Slope = 0 0525152187

Intercept = 0 00518386732

R-Squared = 0 9993

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 22
 Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	5093329 95	501396 619	10 158285	1	193		196		2 8
2	0 00	4993767 789	490648 538	10 177892	1	194				
3	0 00	5604792 485	570393 944	9 826178	1	187				
4	0 00	5219634 05	508815 592	10 258400	1	195				
5	0 00	4582231 216	444390 554	10 311271	1	196				
90	0 00	5258121 199	495274 368	10 616583	1	202				
91	0 00	5945571 994	557494 39	10 664810	1	203				
30	3 00	92266 922	574202 119	0 160687	1	2 96	-1 3	2 97	-1 0	0 5
63	3 00	101439 606	627668 352	0 161613	1	2 98	-0 7			
41	37 5	1179344 47	602310 087	1 958035	1	37 2	-0 8	37 5	0 0	0 9
74	37 5	1571834 517	792544 63	1 983276	1	37 7	0 5			
52	150	4715172 505	612646 618	7 696398	1	146	-2 7	148	-1 3	1 4
88	150	4588594 932	585875 903	7 832025	1	149	-0 7			

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)
 AAR - Concentration Found is Greater than 200 (Highest Standard)

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 22
Serum, Concentration of Cotinine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
08	N/A	1 / Day 1 - 0 0333h	4262685 412	534017 71	7 982292	1	152	23	05104620000561	AA97220-01 05104620000561 08 N/A Serum-1 1 / Day 1 - 0333h
08	N/A	1 / Day 1 - 0 0333h	4308287 19	583791 683	7 379837	1	140	22	05104620000577	AA97220-01 05104620000577 08 N/A Serum-1 1 / Day 1 - 0333h
08	N/A	1 / Day 1 - 0 0333h	3360212 195	532760 961	6 307167	1	120	20	05104620000593	AA97220-01 05104620000593 08 N/A Serum-1 1 / Day 1 - 0333h
08	N/A	1 / Day 1 - 0 0333h	3658419 086	577749 886	6 332185	1	120	21	05104620000609	AA97220-01 05104620000609 08 N/A Serum-1 1 / Day 1 - 0333h
08	N/A	2 / Day 1 0h	4773428 002	532329 955	8 967048	1	171	25	05104620000562	AA97220-01 05104620000562 08 N/A Serum-1 2 / Day 1 0h
08	N/A	2 / Day 1 0h	4340797 185	576711 549	7 526808	1	143	24	05104620000578	AA97220-01 05104620000578 08 N/A Serum-1 2 / Day 1 0h
08	N/A	2 / Day 1 0h	3628831 992	573017 798	6 332843	1	120	26	05104620000594	AA97220-01 05104620000594 08 N/A Serum-1 2 / Day 1 0h
08	N/A	2 / Day 1 0h	3347657 282	505712 47	6 619685	1	126	27	05104620000610	AA97220-01 05104620000610 08 N/A Serum-1 2 / Day 1 0h
08	N/A	3 / Day 1 0 05h	4156340 178	500711 891	8 300862	1	158	31	05104620000563	AA97220-01 05104620000563 08 N/A Serum-1 3 / Day 1 05h
08	N/A	3 / Day 1 0 05h	4271124 117	559714 44	7 630899	1	145	28	05104620000579	AA97220-01 05104620000579 08 N/A Serum-1 3 / Day 1 05h
08	N/A	3 / Day 1 0 05h	3231034 929	515714 115	6 265167	1	119	29	05104620000595	AA97220-01 05104620000595 08 N/A Serum-1 3 / Day 1 05h
08	N/A	3 / Day 1 0 05h	3582222 687	554317 605	6 462401	1	123	32	05104620000611	AA97220-01 05104620000611 08 N/A Serum-1 3 / Day 1 05h
08	N/A	4 / Day 1 0 0833h	4076734 837	540229 855	7 546297	1	144	33	05104620000564	AA97220-01 05104620000564 08 N/A Serum-1 4 / Day 1 0833h
08	N/A	4 / Day 1 0 0833h	4467142 35	550446 742	8 115485	1	154	35	05104620000580	AA97220-01 05104620000580 08 N/A Serum-1 4 / Day 1 0833h
08	N/A	4 / Day 1 0 0833h	3731223 296	557054 14	6 698134	1	127	36	05104620000596	AA97220-01 05104620000596 08 N/A Serum-1 4 / Day 1 0833h
08	N/A	4 / Day 1 0 0833h	3867115 835	548683 076	7 047995	1	134	34	05104620000612	AA97220-01 05104620000612 08 N/A Serum-1 4 / Day 1 0833h
08	N/A	5 / Day 1 0 125h	5397674 029	712647 061	7 574120	1	144	39	05104620000565	AA97220-01 05104620000565 08 N/A Serum-1 5 / Day 1 125h
08	N/A	5 / Day 1 0 125h	4501609 109	608734 597	7 395028	1	141	37	05104620000581	AA97220-01 05104620000581 08 N/A Serum-1 5 / Day 1 125h
08	N/A	5 / Day 1 0 125h	3770252 151	597050 109	6 314800	1	120	38	05104620000613	AA97220-01 05104620000613 08 N/A Serum-1 5 / Day 1 125h
08	N/A	6 / Day 1 0 1667h	4497032 871	560187 207	8 027732	1	153	43	05104620000566	AA97220-01 05104620000566 08 N/A Serum-1 6 / Day 1 1667h
08	N/A	6 / Day 1 0 1667h	4124363 441	568314 318	7 257187	1	138	44	05104620000582	AA97220-01 05104620000582 08 N/A Serum-1 6 / Day 1 1667h
08	N/A	6 / Day 1 0 1667h	3793917 842	582769 854	6 510148	1	124	42	05104620000598	AA97220-01 05104620000598 08 N/A Serum-1 6 / Day 1 1667h
08	N/A	6 / Day 1 0 1667h	4301964 237	687426 503	6 258072	1	119	40	05104620000614	AA97220-01 05104620000614 08 N/A Serum-1 6 / Day 1 1667h
08	N/A	7 / Day 1 0 25h	4502340 778	575518 722	7 823100	1	149	48	05104620000567	AA97220-01 05104620000567 08 N/A Serum-1 7 / Day 1 25h
08	N/A	7 / Day 1 0 25h	4185148 424	542777 264	7 710619	1	147	45	05104620000583	AA97220-01 05104620000583 08 N/A Serum-1 7 / Day 1 25h
08	N/A	7 / Day 1 0 25h	3622809 703	518127 847	6 992115	1	133	47	05104620000599	AA97220-01 05104620000599 08 N/A Serum-1 7 / Day 1 25h
08	N/A	7 / Day 1 0 25h	3684793 852	577871 948	6 376489	1	121	46	05104620000615	AA97220-01 05104620000615 08 N/A Serum-1 7 / Day 1 25h
08	N/A	8 / Day 1 0 333h	4485355 926	587600 514	7 633342	1	145	51	05104620000568	AA97220-01 05104620000568 08 N/A Serum-1 8 / Day 1 333h
08	N/A	8 / Day 1 0 333h	4576694 713	646449 893	7 079736	1	135	53	05104620000584	AA97220-01 05104620000584 08 N/A Serum-1 8 / Day 1 333h
08	N/A	8 / Day 1 0 333h	3571856 859	585189 085	6 103765	1	116	49	05104620000600	AA97220-01 05104620000600 08 N/A Serum-1 8 / Day 1 333h
08	N/A	8 / Day 1 0 333h	3945520 436	625580 253	6 306977	1	120	50	05104620000616	AA97220-01 05104620000616 08 N/A Serum-1 8 / Day 1 333h
08	N/A	9 / Day 1 0 5h	5140934 739	665170 934	7 728742	1	147	55	05104620000569	AA97220-01 05104620000569 08 N/A Serum-1 9 / Day 1 5h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
08	N/A	9 / Day 1 0 5h	4059779 627	560787 549	7 239425	1	138	56	05104620000585	AA97220-01 05104620000585 08 N/A Serum-1 9 / Day 1 5h
08	N/A	9 / Day 1 0 5h	3995223 024	629916 198	6 342468	1	121	54	05104620000601	AA97220-01 05104620000601 08 N/A Serum-1 9 / Day 1 5h
08	N/A	9 / Day 1 0 5h	3733276 132	558280 843	6 687093	1	127	57	05104620000617	AA97220-01 05104620000617 08 N/A Serum-1 9 / Day 1 5h
08	N/A	10 / Day 1 0 75h	4285133 334	553480 668	7 742155	1	147	58	05104620000570	AA97220-01 05104620000570 08 N/A Serum-1 10 / Day 1 75h
08	N/A	10 / Day 1 0 75h	4436221 693	605581 819	7 325553	1	139	60	05104620000586	AA97220-01 05104620000586 08 N/A Serum-1 10 / Day 1 75h
08	N/A	10 / Day 1 0 75h	4227035 381	673583 049	6 275448	1	119	61	05104620000602	AA97220-01 05104620000602 08 N/A Serum-1 10 / Day 1 75h
08	N/A	10 / Day 1 0 75h	4160478 197	639693 856	6 503858	1	124	59	05104620000618	AA97220-01 05104620000618 08 N/A Serum-1 10 / Day 1 75h
08	N/A	11 / Day 1 1h	4990878 97	674697 135	7 397214	1	141	62	05104620000571	AA97220-01 05104620000571 08 N/A Serum-1 11 / Day 1 1h
08	N/A	11 / Day 1 1h	5922536 411	753846 073	7 856427	1	150	64	05104620000587	AA97220-01 05104620000587 08 N/A Serum-1 11 / Day 1 1h
08	N/A	11 / Day 1 1h	3933177 303	579650 025	6 785435	1	129	66	05104620000603	AA97220-01 05104620000603 08 N/A Serum-1 11 / Day 1 1h
08	N/A	11 / Day 1 1h	3672713 493	588493 794	6 240870	1	119	65	05104620000619	AA97220-01 05104620000619 08 N/A Serum-1 11 / Day 1 1h
08	N/A	12 / Day 1 1 25h	4544978 898	612067 603	7 425616	1	141	68	05104620000572	AA97220-01 05104620000572 08 N/A Serum-1 12 / Day 1 1 25h
08	N/A	12 / Day 1 1 25h	4328014 743	580759 302	7 452338	1	142	69	05104620000588	AA97220-01 05104620000588 08 N/A Serum-1 12 / Day 1 1 25h
08	N/A	12 / Day 1 1 25h	3526758 052	560079 507	6 296888	1	120	67	05104620000604	AA97220-01 05104620000604 08 N/A Serum-1 12 / Day 1 1 25h
08	N/A	12 / Day 1 1 25h	4533434 136	721941 512	6 279503	1	119	70	05104620000620	AA97220-01 05104620000620 08 N/A Serum-1 12 / Day 1 1 25h
08	N/A	13 / Day 1 1 5h	6147454 231	852855 087	7 208088	1	137	71	05104620000573	AA97220-01 05104620000573 08 N/A Serum-1 13 / Day 1 1 5h
08	N/A	13 / Day 1 1 5h	6324847 762	832025 258	7 601750	1	145	73	05104620000589	AA97220-01 05104620000589 08 N/A Serum-1 13 / Day 1 1 5h
08	N/A	13 / Day 1 1 5h	5307815 602	792978 702	6 693516	1	127	72	05104620000605	AA97220-01 05104620000605 08 N/A Serum-1 13 / Day 1 1 5h
08	N/A	13 / Day 1 1 5h	5165611 207	832147 694	6 207565	1	118	75	05104620000621	AA97220-01 05104620000621 08 N/A Serum-1 13 / Day 1 1 5h
08	N/A	14 / Day 1 2h	5225269 065	705798 48	7 403344	1	141	79	05104620000574	AA97220-01 05104620000574 08 N/A Serum-1 14 / Day 1 2h
08	N/A	14 / Day 1 2h	5349969 329	756994 483	7 067382	1	134	78	05104620000590	AA97220-01 05104620000590 08 N/A Serum-1 14 / Day 1 2h
08	N/A	14 / Day 1 2h	4718173 293	763506 642	6 179610	1	118	77	05104620000606	AA97220-01 05104620000606 08 N/A Serum-1 14 / Day 1 2h
08	N/A	14 / Day 1 2h	4761719 276	786146 021	6 057042	1	115	76	05104620000622	AA97220-01 05104620000622 08 N/A Serum-1 14 / Day 1 2h
08	N/A	15 / Day 1 2 5h	5828174 384	812782 924	7 170641	1	136	83	05104620000575	AA97220-01 05104620000575 08 N/A Serum-1 15 / Day 1 2 5h
08	N/A	15 / Day 1 2 5h	5850541 638	832793 853	7 025198	1	134	82	05104620000591	AA97220-01 05104620000591 08 N/A Serum-1 15 / Day 1 2 5h
08	N/A	15 / Day 1 2 5h	4523632 172	778042 478	5 814120	1	111	80	05104620000607	AA97220-01 05104620000607 08 N/A Serum-1 15 / Day 1 2 5h
08	N/A	15 / Day 1 2 5h	4692714 632	769336 94	6 099687	1	116	81	05104620000623	AA97220-01 05104620000623 08 N/A Serum-1 15 / Day 1 2 5h
08	N/A	16 / Day 1 3h	5664139 018	815415 979	6 946318	1	132	84	05104620000576	AA97220-01 05104620000576 08 N/A Serum-1 16 / Day 1 3h
08	N/A	16 / Day 1 3h	4017273 578	582970 69	6 891039	1	131	87	05104620000592	AA97220-01 05104620000592 08 N/A Serum-1 16 / Day 1 3h
08	N/A	16 / Day 1 3h	2810831 569	501777 217	5 601752	1	107	85	05104620000608	AA97220-01 05104620000608 08 N/A Serum-1 16 / Day 1 3h
08	N/A	16 / Day 1 3h	3520328 95	566239 527	6 217031	1	118	86	05104620000624	AA97220-01 05104620000624 08 N/A Serum-1 16 / Day 1 3h

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 23
Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		3721 176	2982219 792	0 001248	0 0625		0 0643	4 0
9	0 00		3591 74	2816993 833	0 001275	0 0661			
10	1 00	1 00000	23129 983	2868903 262	0 008062	0 971	-2 9		
11	2 00	0 250000	51163 302	3085205 813	0 016583	2 11	5 5		
12	4 00	0 0625000	97408 68	3114092 316	0 031280	4 07	1 8		
13	8 00	0 0156250	182207 672	2995395 884	0 060829	8 01	0 1		
14	16 0	0 00390625	358053 611	3030796 865	0 118138	15 6	-2 5		
15	40 0	0 000625000	880776 585	3045091 019	0 289245	38 5	-3 8		
16	80 0	0 000156250	1743112 163	2844696 745	0 612759	81 6	2 0		
17	160	0 0000390625	3492701 46	2913524 167	1 198789	160	0 0		
18	200	0 0000250000	4389689 333	2924772 529	1 500865	200	0 0		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:

Slope = 0 00750004739

Intercept = 0 000779203134

R-Squared = 0 9989

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 23
 Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	4704369 281	3178123 09	1 480235	1	197		201		1 1
2	0 00	4554623 16	3016456 278	1 509925	1	201				
3	0 00	4614230 058	3077367 171	1 499408	1	200				
4	0 00	4819073 757	3208620 282	1 501915	1	200				
5	0 00	4586939 274	3038921 009	1 509397	1	201				
95	0 00	5759068 158	3766827 808	1 528891	1	204				
96	0 00	5689955 383	3744365 062	1 519605	1	203				
36	3 00	71820 222	3115139 988	0 023055	1	2 97	-1 0	2 95	-1 7	1 0
68	3 00	82602 817	3630923 174	0 022750	1	2 93	-2 3			
44	37 5	862607 388	3190985 043	0 270326	1	35 9	-4 3	35 5	-5 3	1 6
76	37 5	998526 939	3782915 025	0 263957	1	35 1	-6 4			
27	150	598575 698	2821413 693	0 212155	5	141	-6 0	140	-6 7	1 2
60	150	665231 937	3144301 368	0 211567	5	141	-6 0			
84	150	846905 408	4067439 762	0 208216	5	138	-8 0			
52	150	3587685 562	3331521 654	1 076891	1	143	-4 7	146	-2 7	2 9
93	150	4106656 425	3675405 416	1 117334	1	149	-0 7			

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)
 AAR - Concentration Found is Greater than 200 (Highest Standard)

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 23
Serum, Concentration of Cotinine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
09	N/A	1 / Day 1 -0 0333h	947505 204	2990191 361	0 316871	5	211	21	05104620000657	AA97220-01 05104620000657 09 N/A Serum-1 1 / Day 1 - 0333h
09	N/A	1 / Day 1 -0 0333h	872426 508	2758422 659	0 316277	5	210	22	05104620000673	AA97220-01 05104620000673 09 N/A Serum-1 1 / Day 1 - 0333h
09	N/A	1 / Day 1 -0 0333h	1078494 307	2876558 732	0 374925	5	249	23	05104620000689	AA97220-01 05104620000689 09 N/A Serum-1 1 / Day 1 - 0333h
09	N/A	1 / Day 1 -0 0333h	4583932 236	3015409 191	*1 520169	1	*AAR>(200)	20	05104620000705	AA97220-01 05104620000705 09 N/A Serum-1 1 / Day 1 - 0333h
09	N/A	2 / Day 1 0h	892190 044	2864962 042	0 311414	5	207	28	05104620000658	AA97220-01 05104620000658 09 N/A Serum-1 2 / Day 1 0h
09	N/A	2 / Day 1 0h	4718216 383	3080348 917	*1 531715	1	*AAR>(200)	29	05104620000658	AA97220-01 05104620000658 09 N/A Serum-1 2 / Day 1 0h
09	N/A	2 / Day 1 0h	929117 673	2869546 441	0 323786	5	215	26	05104620000674	AA97220-01 05104620000674 09 N/A Serum-1 2 / Day 1 0h
09	N/A	2 / Day 1 0h	1061093 216	2845396 328	0 372916	5	248	25	05104620000690	AA97220-01 05104620000690 09 N/A Serum-1 2 / Day 1 0h
09	N/A	2 / Day 1 0h	868746 579	2824368 675	0 307590	5	205	24	05104620000706	AA97220-01 05104620000706 09 N/A Serum-1 2 / Day 1 0h
09	N/A	3 / Day 1 0 05h	896117 019	3007243 424	0 297986	5	198	30	05104620000659	AA97220-01 05104620000659 09 N/A Serum-1 3 / Day 1 05h
09	N/A	3 / Day 1 0 05h	994626 216	3136352 472	0 317128	5	211	31	05104620000675	AA97220-01 05104620000675 09 N/A Serum-1 3 / Day 1 05h
09	N/A	3 / Day 1 0 05h	1139644 87	2998255 183	0 380103	5	253	32	05104620000691	AA97220-01 05104620000691 09 N/A Serum-1 3 / Day 1 05h
09	N/A	3 / Day 1 0 05h	1009999 066	3293647 396	0 306651	5	204	33	05104620000707	AA97220-01 05104620000707 09 N/A Serum-1 3 / Day 1 05h
09	N/A	4 / Day 1 0 0833h	964178 763	3057823 39	0 315315	5	210	37	05104620000660	AA97220-01 05104620000660 09 N/A Serum-1 4 / Day 1 0833h
09	N/A	4 / Day 1 0 0833h	1076554 096	3433272 608	0 313565	5	209	34	05104620000676	AA97220-01 05104620000676 09 N/A Serum-1 4 / Day 1 0833h
09	N/A	4 / Day 1 0 0833h	1295118 72	3452032 608	0 375176	5	250	38	05104620000692	AA97220-01 05104620000692 09 N/A Serum-1 4 / Day 1 0833h
09	N/A	4 / Day 1 0 0833h	976576 76	3157105 641	0 309327	5	206	35	05104620000708	AA97220-01 05104620000708 09 N/A Serum-1 4 / Day 1 0833h
09	N/A	5 / Day 1 0 125h	971967 492	3169191 082	0 306693	5	204	41	05104620000661	AA97220-01 05104620000661 09 N/A Serum-1 5 / Day 1 125h
09	N/A	5 / Day 1 0 125h	947884 765	3022290 938	0 313631	5	209	42	05104620000677	AA97220-01 05104620000677 09 N/A Serum-1 5 / Day 1 125h
09	N/A	5 / Day 1 0 125h	1135764 179	3113420 118	0 364796	5	243	39	05104620000693	AA97220-01 05104620000693 09 N/A Serum-1 5 / Day 1 125h
09	N/A	5 / Day 1 0 125h	969858 532	3228847 863	0 300373	5	200	40	05104620000709	AA97220-01 05104620000709 09 N/A Serum-1 5 / Day 1 125h
09	N/A	6 / Day 1 0 1667h	930430 393	3114937 006	0 298700	5	199	46	05104620000662	AA97220-01 05104620000662 09 N/A Serum-1 6 / Day 1 1667h
09	N/A	6 / Day 1 0 1667h	982284 927	3073390 58	0 319610	5	213	47	05104620000678	AA97220-01 05104620000678 09 N/A Serum-1 6 / Day 1 1667h
09	N/A	6 / Day 1 0 1667h	1079426 268	2943496 433	0 366716	5	244	45	05104620000694	AA97220-01 05104620000694 09 N/A Serum-1 6 / Day 1 1667h
09	N/A	6 / Day 1 0 1667h	998529 115	3327429 419	0 300090	5	200	43	05104620000710	AA97220-01 05104620000710 09 N/A Serum-1 6 / Day 1 1667h
09	N/A	7 / Day 1 0 25h	994935 718	3270396 124	0 304225	5	202	50	05104620000663	AA97220-01 05104620000663 09 N/A Serum-1 7 / Day 1 25h
09	N/A	7 / Day 1 0 25h	1013105 634	3254450 385	0 311299	5	207	49	05104620000679	AA97220-01 05104620000679 09 N/A Serum-1 7 / Day 1 25h
09	N/A	7 / Day 1 0 25h	1149592 876	3181602 462	0 361325	5	240	48	05104620000695	AA97220-01 05104620000695 09 N/A Serum-1 7 / Day 1 25h
09	N/A	7 / Day 1 0 25h	987718 71	3137685 992	0 314792	5	209	51	05104620000711	AA97220-01 05104620000711 09 N/A Serum-1 7 / Day 1 25h
09	N/A	8 / Day 1 0 333h	1050316 468	3444857 681	0 304894	5	203	56	05104620000664	AA97220-01 05104620000664 09 N/A Serum-1 8 / Day 1 333h
09	N/A	8 / Day 1 0 333h	1131931 46	3436891 952	0 329347	5	219	53	05104620000680	AA97220-01 05104620000680 09 N/A Serum-1 8 / Day 1 333h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
09	N/A	8 / Day 1 0 333h	1351561 672	3606143 782	0 374794	5	249	54	05104620000696	AA97220-01 05104620000696 09 N/A Serum-1 8 / Day 1 333h
09	N/A	8 / Day 1 0 333h	974658 052	3264542 858	0 298559	5	199	55	05104620000712	AA97220-01 05104620000712 09 N/A Serum-1 8 / Day 1 333h
09	N/A	9 / Day 1 0 5h	1015448 586	3265609 131	0 310952	5	207	58	05104620000665	AA97220-01 05104620000665 09 N/A Serum-1 9 / Day 1 5h
09	N/A	9 / Day 1 0 5h	1030324 242	3301326 515	0 312094	5	208	57	05104620000681	AA97220-01 05104620000681 09 N/A Serum-1 9 / Day 1 5h
09	N/A	9 / Day 1 0 5h	1176762 641	3224556 217	0 364938	5	243	59	05104620000697	AA97220-01 05104620000697 09 N/A Serum-1 9 / Day 1 5h
09	N/A	9 / Day 1 0 5h	815058 155	2656047 341	0 306869	5	204	61	05104620000713	AA97220-01 05104620000713 09 N/A Serum-1 9 / Day 1 5h
09	N/A	10 / Day 1 0 75h	1011717 172	3388760 284	0 298551	5	199	62	05104620000666	AA97220-01 05104620000666 09 N/A Serum-1 10 / Day 1 75h
09	N/A	10 / Day 1 0 75h	1022401 325	3329514 415	0 307072	5	204	63	05104620000682	AA97220-01 05104620000682 09 N/A Serum-1 10 / Day 1 75h
09	N/A	10 / Day 1 0 75h	1192740 329	3397939 416	0 351019	5	233	64	05104620000698	AA97220-01 05104620000698 09 N/A Serum-1 10 / Day 1 75h
09	N/A	10 / Day 1 0 75h	1101283 598	3555647 034	0 309728	5	206	65	05104620000714	AA97220-01 05104620000714 09 N/A Serum-1 10 / Day 1 75h
09	N/A	11 / Day 1 1h	1045248 5	3575060 716	0 292372	5	194	70	05104620000667	AA97220-01 05104620000667 09 N/A Serum-1 11 / Day 1 1h
09	N/A	11 / Day 1 1h	1151748 098	3769995 093	0 305504	5	203	66	05104620000683	AA97220-01 05104620000683 09 N/A Serum-1 11 / Day 1 1h
09	N/A	11 / Day 1 1h	1335627 175	3596341 308	0 371385	5	247	69	05104620000699	AA97220-01 05104620000699 09 N/A Serum-1 11 / Day 1 1h
09	N/A	11 / Day 1 1h	1102771 181	3633006 2	0 303542	5	202	67	05104620000715	AA97220-01 05104620000715 09 N/A Serum-1 11 / Day 1 1h
09	N/A	12 / Day 1 1 25h	1117609 77	3817607 796	0 292751	5	195	74	05104620000668	AA97220-01 05104620000668 09 N/A Serum-1 12 / Day 1 1 25h
09	N/A	12 / Day 1 1 25h	1115054 057	3763991 859	0 296242	5	197	72	05104620000684	AA97220-01 05104620000684 09 N/A Serum-1 12 / Day 1 1 25h
09	N/A	12 / Day 1 1 25h	1274255 79	3578482 845	0 356088	5	237	71	05104620000700	AA97220-01 05104620000700 09 N/A Serum-1 12 / Day 1 1 25h
09	N/A	12 / Day 1 1 25h	1173438 217	4028501 702	0 291284	5	194	73	05104620000716	AA97220-01 05104620000716 09 N/A Serum-1 12 / Day 1 1 25h
09	N/A	13 / Day 1 1 5h	1152959 042	3907947 135	0 295029	5	196	77	05104620000669	AA97220-01 05104620000669 09 N/A Serum-1 13 / Day 1 1 5h
09	N/A	13 / Day 1 1 5h	1158720 832	3916234 767	0 295876	5	197	78	05104620000685	AA97220-01 05104620000685 09 N/A Serum-1 13 / Day 1 1 5h
09	N/A	13 / Day 1 1 5h	1455593 23	4007208 218	0 363244	5	242	79	05104620000701	AA97220-01 05104620000701 09 N/A Serum-1 13 / Day 1 1 5h
09	N/A	13 / Day 1 1 5h	1173983 615	3717270 409	0 315819	5	210	75	05104620000717	AA97220-01 05104620000717 09 N/A Serum-1 13 / Day 1 1 5h
09	N/A	14 / Day 1 2h	1118458 28	3935851 352	0 284172	5	189	82	05104620000670	AA97220-01 05104620000670 09 N/A Serum-1 14 / Day 1 2h
09	N/A	14 / Day 1 2h	1068600 001	3611551 243	0 295884	5	197	83	05104620000686	AA97220-01 05104620000686 09 N/A Serum-1 14 / Day 1 2h
09	N/A	14 / Day 1 2h	1325469 167	3824086 863	0 346611	5	231	80	05104620000702	AA97220-01 05104620000702 09 N/A Serum-1 14 / Day 1 2h
09	N/A	14 / Day 1 2h	1005664 173	3560708 736	0 282434	5	188	81	05104620000718	AA97220-01 05104620000718 09 N/A Serum-1 14 / Day 1 2h
09	N/A	15 / Day 1 2 5h	1046984 57	3800531 952	0 275484	5	183	88	05104620000671	AA97220-01 05104620000671 09 N/A Serum-1 15 / Day 1 2 5h
09	N/A	15 / Day 1 2 5h	1067123 224	3712187 148	0 287465	5	191	85	05104620000687	AA97220-01 05104620000687 09 N/A Serum-1 15 / Day 1 2 5h
09	N/A	15 / Day 1 2 5h	1407502 143	4042474 51	0 348178	5	232	87	05104620000703	AA97220-01 05104620000703 09 N/A Serum-1 15 / Day 1 2 5h
09	N/A	15 / Day 1 2 5h	1100509 095	4041064 604	0 272331	5	181	86	05104620000719	AA97220-01 05104620000719 09 N/A Serum-1 15 / Day 1 2 5h
09	N/A	16 / Day 1 3h	1002915 499	3826817 076	0 262076	5	174	91	05104620000672	AA97220-01 05104620000672 09 N/A Serum-1 16 / Day 1 3h
09	N/A	16 / Day 1 3h	1162201 537	4178989 753	0 278106	5	185	92	05104620000688	AA97220-01 05104620000688 09 N/A Serum-1 16 / Day 1 3h
09	N/A	16 / Day 1 3h	1350793 797	4094965 899	0 329867	5	219	89	05104620000704	AA97220-01 05104620000704 09 N/A Serum-1 16 / Day 1 3h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
09	N/A	16 / Day 1 3h	1179053 063	4128797 998	0 285568	5	190	90	05104620000720	AA97220-01 05104620000720 09 N/A Serum-1 16 / Day 1 3h

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

* - Sample Rejected

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 25
 Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		0	3392476 79	0 000000	-0 0133		-0 0133	0 0
9	0 00		0	3528801 602	0 000000	-0 0133			
10	1 00	1 00000	26478 792	3423726 799	0 007734	0 989	-1 1		
11	2 00	0 250000	57052 108	3681885 803	0 015495	1 99	-0 5		
12	4 00	0 0625000	121733 565	3738656 018	0 032561	4 20	5 0		
13	8 00	0 0156250	189609 263	3024045 324	0 062701	8 11	1 4		
14	16 0	0 00390625	358628 822	2946563 863	0 121711	15 8	-1 3		
15	40 0	0 000625000	1037424 039	3421275 288	0 303227	39 3	-1 8		
16	80 0	0 000156250	2194830 595	3561787 257	0 616216	79 8	-0 3		
17	160	0 0000390625	4416880 941	3581375 928	1 233292	160	0 0		
18	200	0 0000250000	5531712 273	3628778 934	1 524400	197	-1 5		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:

Slope = 0 00771947342

Intercept = 0 000102958693

R-Squared = 0 9994

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 25
Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	4944479 571	3312304 596	1 492761	1	193		197		1 0
2	0 00	4795654 297	3160470 593	1 517386	1	197				
3	0 00	4955862 812	3265158 8	1 517801	1	197				
4	0 00	5182821 116	3398939 997	1 524835	1	198				
5	0 00	5265210 299	3441971 383	1 529708	1	198				
94	0 00	4653128 75	3033653 688	1 533836	1	199				
95	0 00	4757050 537	3120169 349	1 524613	1	197				
35	3 00	67592 578	3128265 923	0 021607	1	2 79	-7 0	2 97	-1 0	8 3
67	3 00	78586 345	3225422 98	0 024365	1	3 14	4 7			
43	37 5	865578 017	3011195 696	0 287453	1	37 2	-0 8	36 7	-2 1	2 1
75	37 5	785278 677	2813340 892	0 279127	1	36 1	-3 7			
27	150	840434 528	3798712 88	0 221242	5	143	-4 7	143	-4 7	2 1
59	150	767206 907	3544397 008	0 216456	5	140	-6 7			
83	150	562034 07	2497788 799	0 225013	5	146	-2 7			
51	150	3225523 545	2943128 541	1 095951	1	142	-5 3	143	-4 7	0 5
92	150	3311116 783	2996037 874	1 105165	1	143	-4 7			

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 25
Serum, Concentration of Cotinine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
09	N/A	1 / Day 1 - 0 0333h	1333524 152	3531280 782	0 377632	5	245	20	05104620000641	AA97220-01 05104620000641 09 N/A Serum-1 1 / Day 1 - 0333h
09	N/A	2 / Day 1 0h	1206709 423	3242848 671	0 372114	5	241	21	05104620000642	AA97220-01 05104620000642 09 N/A Serum-1 2 / Day 1 0h
09	N/A	3 / Day 1 0 05h	1409184 165	3824625 157	0 368450	5	239	22	05104620000643	AA97220-01 05104620000643 09 N/A Serum-1 3 / Day 1 05h
09	N/A	4 / Day 1 0 0833h	1312406 627	3655797 096	0 358993	5	232	23	05104620000644	AA97220-01 05104620000644 09 N/A Serum-1 4 / Day 1 0833h
09	N/A	5 / Day 1 0 125h	1282479 772	3594417 443	0 356798	5	231	24	05104620000645	AA97220-01 05104620000645 09 N/A Serum-1 5 / Day 1 125h
09	N/A	6 / Day 1 0 1667h	1377552 692	3880596 748	0 354985	5	230	25	05104620000646	AA97220-01 05104620000646 09 N/A Serum-1 6 / Day 1 1667h
09	N/A	7 / Day 1 0 25h	1125178 833	3126708 383	0 359860	5	233	26	05104620000647	AA97220-01 05104620000647 09 N/A Serum-1 7 / Day 1 25h
09	N/A	8 / Day 1 0 333h	1245264 476	3463363 149	0 359554	5	233	28	05104620000648	AA97220-01 05104620000648 09 N/A Serum-1 8 / Day 1 333h
09	N/A	9 / Day 1 0 5h	1373874 869	3656364 562	0 375749	5	243	29	05104620000649	AA97220-01 05104620000649 09 N/A Serum-1 9 / Day 1 5h
09	N/A	10 / Day 1 0 75h	1409427 105	3888813 273	0 362431	5	235	30	05104620000650	AA97220-01 05104620000650 09 N/A Serum-1 10 / Day 1 75h
09	N/A	11 / Day 1 1h	1197661 426	3370053 821	0 355383	5	230	31	05104620000651	AA97220-01 05104620000651 09 N/A Serum-1 11 / Day 1 1h
09	N/A	12 / Day 1 1 25h	1235328 68	3371789 725	0 366372	5	237	32	05104620000652	AA97220-01 05104620000652 09 N/A Serum-1 12 / Day 1 1 25h
09	N/A	13 / Day 1 1 5h	1172213 917	3392469 466	0 345534	5	224	33	05104620000653	AA97220-01 05104620000653 09 N/A Serum-1 13 / Day 1 1 5h
09	N/A	14 / Day 1 2h	1209957 99	3529678 58	0 342796	5	222	34	05104620000654	AA97220-01 05104620000654 09 N/A Serum-1 14 / Day 1 2h
09	N/A	15 / Day 1 2 5h	1026961 286	3005244 514	0 341723	5	221	36	05104620000655	AA97220-01 05104620000655 09 N/A Serum-1 15 / Day 1 2 5h
09	N/A	16 / Day 1 3h	982632 662	2921105 771	0 336391	5	218	37	05104620000656	AA97220-01 05104620000656 09 N/A Serum-1 16 / Day 1 3h
10	N/A	1 / Day 1 - 0 0333h	1729190 89	3261045 253	0 530257	5	343	39	05104620000753	AA97220-01 05104620000753 10 N/A Serum-1 1 / Day 1 - 0333h
10	N/A	1 / Day 1 - 0 0333h	1374358 376	3522540 706	0 390161	5	253	40	05104620000769	AA97220-01 05104620000769 10 N/A Serum-1 1 / Day 1 - 0333h
10	N/A	1 / Day 1 - 0 0333h	1144508 842	3450126 147	0 331730	5	215	38	05104620000785	AA97220-01 05104620000785 10 N/A Serum-1 1 / Day 1 - 0333h
10	N/A	2 / Day 1 0h	1860003 465	3663031 255	0 507777	5	329	42	05104620000754	AA97220-01 05104620000754 10 N/A Serum-1 2 / Day 1 0h
10	N/A	2 / Day 1 0h	1331504 237	3469642 329	0 383758	5	248	41	05104620000770	AA97220-01 05104620000770 10 N/A Serum-1 2 / Day 1 0h
10	N/A	2 / Day 1 0h	1118606 24	3172028 964	0 352647	5	228	44	05104620000786	AA97220-01 05104620000786 10 N/A Serum-1 2 / Day 1 0h
10	N/A	3 / Day 1 0 05h	1533116 123	2913175 432	0 526270	5	341	45	05104620000755	AA97220-01 05104620000755 10 N/A Serum-1 3 / Day 1 05h
10	N/A	3 / Day 1 0 05h	1204199 46	3106574 025	0 387629	5	251	46	05104620000771	AA97220-01 05104620000771 10 N/A Serum-1 3 / Day 1 05h
10	N/A	3 / Day 1 0 05h	966571 283	2922222 165	0 330766	5	214	47	05104620000787	AA97220-01 05104620000787 10 N/A Serum-1 3 / Day 1 05h
10	N/A	4 / Day 1 0 0833h	1610972 823	3060735 298	0 526335	5	341	49	05104620000756	AA97220-01 05104620000756 10 N/A Serum-1 4 / Day 1 0833h
10	N/A	4 / Day 1 0 0833h	1174401 553	2892614 868	0 406000	5	263	48	05104620000772	AA97220-01 05104620000772 10 N/A Serum-1 4 / Day 1 0833h
10	N/A	4 / Day 1 0 0833h	1026147 033	3107553 316	0 330211	5	214	50	05104620000788	AA97220-01 05104620000788 10 N/A Serum-1 4 / Day 1 0833h
10	N/A	5 / Day 1 0 125h	1707184 88	3308781 229	0 515956	5	334	54	05104620000757	AA97220-01 05104620000757 10 N/A Serum-1 5 / Day 1 125h
10	N/A	5 / Day 1 0 125h	1000863 157	2611181 724	0 383299	5	248	52	05104620000773	AA97220-01 05104620000773 10 N/A Serum-1 5 / Day 1 125h
10	N/A	5 / Day 1 0 125h	1052739 12	2659929 699	0 395777	5	256	53	05104620000789	AA97220-01 05104620000789 10 N/A Serum-1 5 / Day 1 125h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
10	N/A	6 / Day 1 0 1667h	1845215 301	3572725 132	0 516473	5	334	56	05104620000758	AA97220-01 05104620000758 10 N/A Serum-1 6 / Day 1 1667h
10	N/A	6 / Day 1 0 1667h	1335679 327	3545531 984	0 376722	5	244	57	05104620000774	AA97220-01 05104620000774 10 N/A Serum-1 6 / Day 1 1667h
10	N/A	6 / Day 1 0 1667h	1147238 268	3410997 09	0 336335	5	218	55	05104620000790	AA97220-01 05104620000790 10 N/A Serum-1 6 / Day 1 1667h
10	N/A	7 / Day 1 0 25h	1859452 188	3634465 154	0 511616	5	331	58	05104620000759	AA97220-01 05104620000759 10 N/A Serum-1 7 / Day 1 25h
10	N/A	7 / Day 1 0 25h	1349834 747	3538502 058	0 381471	5	247	60	05104620000775	AA97220-01 05104620000775 10 N/A Serum-1 7 / Day 1 25h
10	N/A	7 / Day 1 0 25h	1204843 621	3611451 343	0 333618	5	216	61	05104620000791	AA97220-01 05104620000791 10 N/A Serum-1 7 / Day 1 25h
10	N/A	8 / Day 1 0 333h	1700082 371	3369639 557	0 504529	5	327	62	05104620000760	AA97220-01 05104620000760 10 N/A Serum-1 8 / Day 1 333h
10	N/A	8 / Day 1 0 333h	1267921 467	3321035 075	0 381785	5	247	63	05104620000776	AA97220-01 05104620000776 10 N/A Serum-1 8 / Day 1 333h
10	N/A	8 / Day 1 0 333h	1059190 992	3194388 287	0 331579	5	215	64	05104620000792	AA97220-01 05104620000792 10 N/A Serum-1 8 / Day 1 333h
10	N/A	9 / Day 1 0 5h	1603357 275	3168324 915	0 506058	5	328	66	05104620000761	AA97220-01 05104620000761 10 N/A Serum-1 9 / Day 1 5h
10	N/A	9 / Day 1 0 5h	1153215 041	3050506 735	0 378040	5	245	68	05104620000777	AA97220-01 05104620000777 10 N/A Serum-1 9 / Day 1 5h
10	N/A	9 / Day 1 0 5h	1054377 805	3192291 468	0 330289	5	214	65	05104620000793	AA97220-01 05104620000793 10 N/A Serum-1 9 / Day 1 5h
10	N/A	10 / Day 1 0 75h	1506629 816	2882746 663	0 522637	5	338	69	05104620000762	AA97220-01 05104620000762 10 N/A Serum-1 10 / Day 1 75h
10	N/A	10 / Day 1 0 75h	1230220 992	3093284 956	0 397707	5	258	71	05104620000778	AA97220-01 05104620000778 10 N/A Serum-1 10 / Day 1 75h
10	N/A	10 / Day 1 0 75h	990238 75	2927159 56	0 338293	5	219	70	05104620000794	AA97220-01 05104620000794 10 N/A Serum-1 10 / Day 1 75h
10	N/A	11 / Day 1 1h	1602762 219	3080990 814	0 520210	5	337	73	05104620000763	AA97220-01 05104620000763 10 N/A Serum-1 11 / Day 1 1h
10	N/A	11 / Day 1 1h	1334620 292	3363639 519	0 396779	5	257	74	05104620000779	AA97220-01 05104620000779 10 N/A Serum-1 11 / Day 1 1h
10	N/A	11 / Day 1 1h	941336 289	2849030 976	0 330406	5	214	72	05104620000795	AA97220-01 05104620000795 10 N/A Serum-1 11 / Day 1 1h
10	N/A	12 / Day 1 1 25h	1366491 292	2661549 709	0 513419	5	332	78	05104620000764	AA97220-01 05104620000764 10 N/A Serum-1 12 / Day 1 1 25h
10	N/A	12 / Day 1 1 25h	1227361 998	3087658 351	0 397506	5	257	76	05104620000780	AA97220-01 05104620000780 10 N/A Serum-1 12 / Day 1 1 25h
10	N/A	12 / Day 1 1 25h	946742 893	2887538 889	0 327872	5	212	77	05104620000796	AA97220-01 05104620000796 10 N/A Serum-1 12 / Day 1 1 25h
10	N/A	13 / Day 1 1 5h	1635303 805	3188128 753	0 512935	5	332	81	05104620000765	AA97220-01 05104620000765 10 N/A Serum-1 13 / Day 1 1 5h
10	N/A	13 / Day 1 1 5h	1312907 681	3174873 357	0 413531	5	268	79	05104620000781	AA97220-01 05104620000781 10 N/A Serum-1 13 / Day 1 1 5h
10	N/A	13 / Day 1 1 5h	1096862 199	3190823 768	0 343755	5	223	80	05104620000797	AA97220-01 05104620000797 10 N/A Serum-1 13 / Day 1 1 5h
10	N/A	14 / Day 1 2h	1619001 041	3223177 353	0 502300	5	325	82	05104620000766	AA97220-01 05104620000766 10 N/A Serum-1 14 / Day 1 2h
10	N/A	14 / Day 1 2h	1210787 567	2947930 974	0 410725	5	266	84	05104620000782	AA97220-01 05104620000782 10 N/A Serum-1 14 / Day 1 2h
10	N/A	14 / Day 1 2h	1110932 402	3406353 613	0 326135	5	211	85	05104620000798	AA97220-01 05104620000798 10 N/A Serum-1 14 / Day 1 2h
10	N/A	15 / Day 1 2 5h	1641298 877	3459124 638	0 474484	5	307	88	05104620000767	AA97220-01 05104620000767 10 N/A Serum-1 15 / Day 1 2 5h
10	N/A	15 / Day 1 2 5h	1268684 412	3137991 833	0 404298	5	262	86	05104620000783	AA97220-01 05104620000783 10 N/A Serum-1 15 / Day 1 2 5h
10	N/A	15 / Day 1 2 5h	955089 143	2984194 096	0 320049	5	207	87	05104620000799	AA97220-01 05104620000799 10 N/A Serum-1 15 / Day 1 2 5h
10	N/A	16 / Day 1 3h	1557795 834	3168016 163	0 491726	5	318	91	05104620000768	AA97220-01 05104620000768 10 N/A Serum-1 16 / Day 1 3h
10	N/A	16 / Day 1 3h	1283964 138	3252544 886	0 394757	5	256	90	05104620000784	AA97220-01 05104620000784 10 N/A Serum-1 16 / Day 1 3h
10	N/A	16 / Day 1 3h	1021453 97	3294831 076	0 310017	5	201	89	05104620000800	AA97220-01 05104620000800 10 N/A Serum-1 16 / Day 1 3h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1.00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 26
Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		1215 667	3130065 907	0 000388	0 0251		-0 000100	-35600 0
9	0 00		0	2935950 258	0 000000	-0 0253			
10	1 00	1 00000	20319 37	2716885 512	0 007479	0 946	-5 4		
11	2 00	0 250000	50109 309	2911440 124	0 017211	2 21	10 5		
12	4 00	0 0625000	90568 681	2874117 216	0 031512	4 07	1 8		
13	8 00	0 0156250	175098 528	2802179 128	0 062487	8 09	1 1		
14	16 0	0 00390625	334378 06	2868223 812	0 116580	15 1	-5 6		
15	40 0	0 000625000	865370 078	2883808 68	0 300079	38 9	-2 8		
16	80 0	0 000156250	1541528 419	2521846 16	0 611270	79 4	-0 8		
17	160	0 0000390625	3163043 989	2531374 916	1 249536	162	1 3		
18	200	0 0000250000	3807657 865	2481133 999	1 534644	199	-0 5		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:

Slope = 0 00769986220

Intercept = 0 000194605502

R-Squared = 0 9970

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 26
Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	4919653 23	3232957 756	1 521719	1	198		198		0 8
2	0 00	4388211 526	2879352 547	1 524027	1	198				
3	0 00	4487580 149	2959768 542	1 516193	1	197				
4	0 00	4289008 983	2808483 298	1 527162	1	198				
5	0 00	4381313 736	2832840 598	1 546615	1	201				
94	0 00	4649276 261	3052174 427	1 523267	1	198				
95	0 00	4164707 612	2762533 349	1 507568	1	196				
35	3 00	64373 668	2801819 308	0 022976	1	2 96	-1 3	2 97	-1 0	0 2
67	3 00	60742 027	2636005 947	0 023043	1	2 97	-1 0			
43	37 5	834004 412	3014430 535	0 276671	1	35 9	-4 3	35 6	-5 1	1 2
75	37 5	658311 244	2420843 255	0 271935	1	35 3	-5 9			
27	150	561188 774	2548550 828	0 220199	5	143	-4 7	140	-6 7	2 7
59	150	660498 255	3151166 232	0 209604	5	136	-9 3			
83	150	579208 013	2637832 517	0 219577	5	142	-5 3			
51	150	2881244 88	2604545 943	1 106237	1	144	-4 0	143	-4 7	1 0
92	150	3166410 621	2885632 449	1 097302	1	142	-5 3			

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 26
Serum, Concentration of Cotinine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
12	N/A	1 / Day 1 - 0 0333h	2960353 804	2663323 117	1 111526	5	722	22	05104620000881	AA97220-01 05104620000881 12 N/A Serum-1 1 / Day 1 - 0333h
12	N/A	1 / Day 1 - 0 0333h	2666547 107	2747818 37	0 970423	5	630	23	05104620000897	AA97220-01 05104620000897 12 N/A Serum-1 1 / Day 1 - 0333h
12	N/A	1 / Day 1 - 0 0333h	1681858 221	2628021 12	0 639971	5	415	20	05104620000913	AA97220-01 05104620000913 12 N/A Serum-1 1 / Day 1 - 0333h
12	N/A	1 / Day 1 - 0 0333h	1775075 379	2630750 751	0 674741	5	438	21	05104620000929	AA97220-01 05104620000929 12 N/A Serum-1 1 / Day 1 - 0333h
12	N/A	2 / Day 1 0h	2993146 88	2784573 373	1 074903	5	698	26	05104620000882	AA97220-01 05104620000882 12 N/A Serum-1 2 / Day 1 0h
12	N/A	2 / Day 1 0h	2754101 232	2833190 434	0 972085	5	631	25	05104620000898	AA97220-01 05104620000898 12 N/A Serum-1 2 / Day 1 0h
12	N/A	2 / Day 1 0h	1849661 408	2843243 125	0 650546	5	422	24	05104620000914	AA97220-01 05104620000914 12 N/A Serum-1 2 / Day 1 0h
12	N/A	2 / Day 1 0h	1660511 487	2478092 868	0 670076	5	435	28	05104620000930	AA97220-01 05104620000930 12 N/A Serum-1 2 / Day 1 0h
12	N/A	3 / Day 1 0 05h	3916690 4	3496511 949	1 120171	5	727	29	05104620000883	AA97220-01 05104620000883 12 N/A Serum-1 3 / Day 1 05h
12	N/A	3 / Day 1 0 05h	2748936 272	2813688 043	0 976987	5	634	31	05104620000899	AA97220-01 05104620000899 12 N/A Serum-1 3 / Day 1 05h
12	N/A	3 / Day 1 0 05h	1826688 537	2726984 977	0 669856	5	435	32	05104620000915	AA97220-01 05104620000915 12 N/A Serum-1 3 / Day 1 05h
12	N/A	3 / Day 1 0 05h	1993651 449	3087222 751	0 645775	5	419	30	05104620000931	AA97220-01 05104620000931 12 N/A Serum-1 3 / Day 1 05h
12	N/A	4 / Day 1 0 0833h	3238314 385	2898080 608	1 117400	5	725	37	05104620000884	AA97220-01 05104620000884 12 N/A Serum-1 4 / Day 1 0833h
12	N/A	4 / Day 1 0 0833h	2438131 323	2586537 564	0 942624	5	612	34	05104620000900	AA97220-01 05104620000900 12 N/A Serum-1 4 / Day 1 0833h
12	N/A	4 / Day 1 0 0833h	1754586 623	2690544 2	0 652131	5	423	36	05104620000916	AA97220-01 05104620000916 12 N/A Serum-1 4 / Day 1 0833h
12	N/A	4 / Day 1 0 0833h	1656946 463	2577191 885	0 642927	5	417	33	05104620000932	AA97220-01 05104620000932 12 N/A Serum-1 4 / Day 1 0833h
12	N/A	5 / Day 1 0 125h	3216834 837	3195664 69	1 006625	5	654	38	05104620000885	AA97220-01 05104620000885 12 N/A Serum-1 5 / Day 1 125h
12	N/A	5 / Day 1 0 125h	2822089 848	2650608 397	1 064695	5	691	39	05104620000901	AA97220-01 05104620000901 12 N/A Serum-1 5 / Day 1 125h
12	N/A	5 / Day 1 0 125h	1912775 17	2941476 295	0 650277	5	422	40	05104620000917	AA97220-01 05104620000917 12 N/A Serum-1 5 / Day 1 125h
12	N/A	5 / Day 1 0 125h	2051589 57	3106189 678	0 660484	5	429	41	05104620000933	AA97220-01 05104620000933 12 N/A Serum-1 5 / Day 1 125h
12	N/A	6 / Day 1 0 1667h	3021977 23	2659283 876	1 136388	5	738	42	05104620000886	AA97220-01 05104620000886 12 N/A Serum-1 6 / Day 1 1667h
12	N/A	6 / Day 1 0 1667h	2742195 146	2942466 832	0 931937	5	605	45	05104620000902	AA97220-01 05104620000902 12 N/A Serum-1 6 / Day 1 1667h
12	N/A	6 / Day 1 0 1667h	1806897 806	2808974 044	0 643259	5	418	46	05104620000918	AA97220-01 05104620000918 12 N/A Serum-1 6 / Day 1 1667h
12	N/A	6 / Day 1 0 1667h	2006082 868	3017909 23	0 664726	5	432	44	05104620000934	AA97220-01 05104620000934 12 N/A Serum-1 6 / Day 1 1667h
12	N/A	7 / Day 1 0 25h	2900473 707	2635743 91	1 100438	5	714	50	05104620000887	AA97220-01 05104620000887 12 N/A Serum-1 7 / Day 1 25h
12	N/A	7 / Day 1 0 25h	3100930 469	3243082 89	0 956168	5	621	49	05104620000903	AA97220-01 05104620000903 12 N/A Serum-1 7 / Day 1 25h
12	N/A	7 / Day 1 0 25h	1867421 908	2857837 977	0 653439	5	424	48	05104620000919	AA97220-01 05104620000919 12 N/A Serum-1 7 / Day 1 25h
12	N/A	7 / Day 1 0 25h	1917531 727	2904093 397	0 660286	5	429	47	05104620000935	AA97220-01 05104620000935 12 N/A Serum-1 7 / Day 1 25h
12	N/A	8 / Day 1 0 333h	2881107 169	2619793 727	1 099746	5	714	53	05104620000888	AA97220-01 05104620000888 12 N/A Serum-1 8 / Day 1 333h
12	N/A	8 / Day 1 0 333h	2637308 199	2840442 38	0 928485	5	603	54	05104620000904	AA97220-01 05104620000904 12 N/A Serum-1 8 / Day 1 333h
12	N/A	8 / Day 1 0 333h	2020178 66	3015064 568	0 670028	5	435	55	05104620000920	AA97220-01 05104620000920 12 N/A Serum-1 8 / Day 1 333h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
12	N/A	8 / Day 1 0 333h	1780131 088	2732622 671	0 651437	5	423	52	05104620000936	AA97220-01 05104620000936 12 N/A Serum-1 8 / Day 1 333h
12	N/A	9 / Day 1 0 5h	3083628 409	2473409 612	1 246712	5	809	60	05104620000889	AA97220-01 05104620000889 12 N/A Serum-1 9 / Day 1 5h
12	N/A	9 / Day 1 0 5h	2474584 963	2664039 418	0 928885	5	603	58	05104620000905	AA97220-01 05104620000905 12 N/A Serum-1 9 / Day 1 5h
12	N/A	9 / Day 1 0 5h	1807711 041	2786077 979	0 648837	5	421	57	05104620000921	AA97220-01 05104620000921 12 N/A Serum-1 9 / Day 1 5h
12	N/A	9 / Day 1 0 5h	2120387 806	3224797 466	0 657526	5	427	56	05104620000937	AA97220-01 05104620000937 12 N/A Serum-1 9 / Day 1 5h
12	N/A	10 / Day 1 0 75h	3047474 818	2723857 472	1 118808	5	726	63	05104620000890	AA97220-01 05104620000890 12 N/A Serum-1 10 / Day 1 75h
12	N/A	10 / Day 1 0 75h	2427020 663	2626620 965	0 924009	5	600	64	05104620000906	AA97220-01 05104620000906 12 N/A Serum-1 10 / Day 1 75h
12	N/A	10 / Day 1 0 75h	1728875 168	2668996 237	0 647762	5	421	62	05104620000922	AA97220-01 05104620000922 12 N/A Serum-1 10 / Day 1 75h
12	N/A	10 / Day 1 0 75h	1865661 752	2752324 649	0 677849	5	440	61	05104620000938	AA97220-01 05104620000938 12 N/A Serum-1 10 / Day 1 75h
12	N/A	11 / Day 1 1h	3027101 831	2764185 511	1 095115	5	711	65	05104620000891	AA97220-01 05104620000891 12 N/A Serum-1 11 / Day 1 1h
12	N/A	11 / Day 1 1h	2302598 076	2607725 791	0 882991	5	573	69	05104620000907	AA97220-01 05104620000907 12 N/A Serum-1 11 / Day 1 1h
12	N/A	11 / Day 1 1h	1845169 417	2636709 813	0 699800	5	454	68	05104620000923	AA97220-01 05104620000923 12 N/A Serum-1 11 / Day 1 1h
12	N/A	11 / Day 1 1h	1814025 474	2810415 526	0 645465	5	419	66	05104620000939	AA97220-01 05104620000939 12 N/A Serum-1 11 / Day 1 1h
12	N/A	12 / Day 1 1 25h	3016200 566	2731226 159	1 104339	5	717	70	05104620000892	AA97220-01 05104620000892 12 N/A Serum-1 12 / Day 1 1 25h
12	N/A	12 / Day 1 1 25h	2367508 038	2616245 806	0 904926	5	587	73	05104620000908	AA97220-01 05104620000908 12 N/A Serum-1 12 / Day 1 1 25h
12	N/A	12 / Day 1 1 25h	1768536 872	2733442 608	0 647000	5	420	72	05104620000924	AA97220-01 05104620000924 12 N/A Serum-1 12 / Day 1 1 25h
12	N/A	12 / Day 1 1 25h	1754888 53	2774895 72	0 632416	5	411	71	05104620000940	AA97220-01 05104620000940 12 N/A Serum-1 12 / Day 1 1 25h
12	N/A	13 / Day 1 1 5h	2842145 101	2696752 669	1 053914	5	684	77	05104620000893	AA97220-01 05104620000893 12 N/A Serum-1 13 / Day 1 1 5h
12	N/A	13 / Day 1 1 5h	2298172 19	2556872 168	0 898822	5	584	76	05104620000909	AA97220-01 05104620000909 12 N/A Serum-1 13 / Day 1 1 5h
12	N/A	13 / Day 1 1 5h	1668308 79	2631016 966	0 634093	5	412	74	05104620000925	AA97220-01 05104620000925 12 N/A Serum-1 13 / Day 1 1 5h
12	N/A	13 / Day 1 1 5h	1661281 309	2588348 378	0 641831	5	417	78	05104620000941	AA97220-01 05104620000941 12 N/A Serum-1 13 / Day 1 1 5h
12	N/A	14 / Day 1 2h	2838199 559	2594868 727	1 093774	5	710	80	05104620000894	AA97220-01 05104620000894 12 N/A Serum-1 14 / Day 1 2h
12	N/A	14 / Day 1 2h	2279049 34	2599923 619	0 876583	5	569	82	05104620000910	AA97220-01 05104620000910 12 N/A Serum-1 14 / Day 1 2h
12	N/A	14 / Day 1 2h	1809467 733	2756652 618	0 656400	5	426	81	05104620000926	AA97220-01 05104620000926 12 N/A Serum-1 14 / Day 1 2h
12	N/A	14 / Day 1 2h	1660065 883	2638337 968	0 629209	5	408	79	05104620000942	AA97220-01 05104620000942 12 N/A Serum-1 14 / Day 1 2h
12	N/A	15 / Day 1 2 5h	2874342 237	2749972 623	1 045226	5	679	84	05104620000895	AA97220-01 05104620000895 12 N/A Serum-1 15 / Day 1 2 5h
12	N/A	15 / Day 1 2 5h	2457106 09	2829931 429	0 868256	5	564	87	05104620000911	AA97220-01 05104620000911 12 N/A Serum-1 15 / Day 1 2 5h
12	N/A	15 / Day 1 2 5h	1947208 291	2932991 119	0 663898	5	431	86	05104620000927	AA97220-01 05104620000927 12 N/A Serum-1 15 / Day 1 2 5h
12	N/A	15 / Day 1 2 5h	1737625 92	2770901 772	0 627098	5	407	85	05104620000943	AA97220-01 05104620000943 12 N/A Serum-1 15 / Day 1 2 5h
12	N/A	16 / Day 1 3h	3015634 599	2870773 717	1 050461	5	682	89	05104620000896	AA97220-01 05104620000896 12 N/A Serum-1 16 / Day 1 3h
12	N/A	16 / Day 1 3h	2497313 346	2865151 731	0 871616	5	566	91	05104620000912	AA97220-01 05104620000912 12 N/A Serum-1 16 / Day 1 3h
12	N/A	16 / Day 1 3h	1346230 094	2070134 114	0 650311	5	422	90	05104620000928	AA97220-01 05104620000928 12 N/A Serum-1 16 / Day 1 3h
12	N/A	16 / Day 1 3h	1801367 847	2825095 843	0 637631	5	414	88	05104620000944	AA97220-01 05104620000944 12 N/A Serum-1 16 / Day 1 3h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1.00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 27
 Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		1588 572	1935677 865	0 000821	-0 0519		-0 0456	-19 5
9	0 00		1825 31	1986164 172	0 000919	-0 0393			
10	1 00	1 00000	16875 557	1978742 701	0 008528	0 943	-5 7		
11	2 00	0 250000	36064 752	1951551 175	0 018480	2 23	11 5		
12	4 00	0 0625000	61471 023	1905364 689	0 032262	4 01	0 3		
13	8 00	0 0156250	126459 438	1984110 329	0 063736	8 07	0 9		
14	16 0	0 00390625	256778 815	2057651 775	0 124792	15 9	-0 6		
15	40 0	0 000625000	668137 423	2148224 342	0 311018	40 0	0 0		
16	80 0	0 000156250	1189252 206	1981872 479	0 600065	77 3	-3 4		
17	160	0 0000390625	2480016 118	2007258 994	1 235524	159	-0 6		
18	200	0 0000250000	2601709 057	1718042 499	1 514345	195	-2 5		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:

Slope = 0 00774886626

Intercept = 0 00122351977

R-Squared = 0 9970

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 27
 Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	2901754 947	1866915 495	1 554304	1	200		201		1 2
2	0 00	3045302 324	2008384 765	1 516294	1	196				
3	0 00	2979469 209	1898544 324	1 569344	1	202				
4	0 00	2936085 584	1866376 764	1 573147	1	203				
5	0 00	3045443 682	1943191 565	1 567238	1	202				
93	0 00	3151627 294	2010520 08	1 567568	1	202				
94	0 00	3334524 501	2138785 206	1 559074	1	201				
35	3 00	42412 657	1846326 168	0 022971	1	2 81	-6 3	2 79	-7 0	1 3
67	3 00	45362 562	2004992 13	0 022625	1	2 76	-8 0			
43	37 5	565070 57	2080035 688	0 271664	1	34 9	-6 9	35 5	-5 3	2 4
75	37 5	520028 651	1848473 384	0 281329	1	36 1	-3 7			
27	150	372710 347	1713013 216	0 217576	5	140	-6 7	139	-7 3	2 9
59	150	412106 172	1847741 101	0 223032	5	143	-4 7			
83	150	393678 566	1867048 872	0 210856	5	135	-10 0			
51	150	2116184 503	1946834 614	1 086987	1	140	-6 7	143	-4 7	3 0
91	150	2310222 356	2044341 388	1 130057	1	146	-2 7			

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)
 AAR - Concentration Found is Greater than 200 (Highest Standard)

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 27
Serum, Concentration of Cotinine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
01	N/A	15 / Day 1 2 5h	1383168 972	1950415 869	0 709166	1	91 4	20	05104620000047	AA97220-01 05104620000047 01 N/A Serum-1 15 / Day 1 2 5h
03	N/A	1 / Day 1 - 0 0333h	675848 04	1839416 988	0 367425	5	236	34	05104620000209	AA97220-01 05104620000209 03 N/A Serum-1 1 / Day 1 - 0333h
03	N/A	1 / Day 1 - 0 0333h	819310 287	1832643 666	0 447065	5	288	36	05104620000225	AA97220-01 05104620000225 03 N/A Serum-1 1 / Day 1 - 0333h
03	N/A	2 / Day 1 0h	778441 468	2047849 385	0 380126	5	244	37	05104620000210	AA97220-01 05104620000210 03 N/A Serum-1 2 / Day 1 0h
03	N/A	2 / Day 1 0h	740861 55	1771145 48	0 418295	5	269	38	05104620000226	AA97220-01 05104620000226 03 N/A Serum-1 2 / Day 1 0h
03	N/A	3 / Day 1 0 05h	780320 088	2019874 153	0 386321	5	248	40	05104620000211	AA97220-01 05104620000211 03 N/A Serum-1 3 / Day 1 05h
03	N/A	3 / Day 1 0 05h	769202 675	1762973 279	0 436310	5	281	39	05104620000227	AA97220-01 05104620000227 03 N/A Serum-1 3 / Day 1 05h
03	N/A	4 / Day 1 0 0833h	756225 028	2017538 006	0 374826	5	241	42	05104620000212	AA97220-01 05104620000212 03 N/A Serum-1 4 / Day 1 0833h
03	N/A	4 / Day 1 0 0833h	849295 969	1944416 395	0 436787	5	281	41	05104620000228	AA97220-01 05104620000228 03 N/A Serum-1 4 / Day 1 0833h
03	N/A	5 / Day 1 0 125h	742649 957	1982827 49	0 374541	5	241	44	05104620000213	AA97220-01 05104620000213 03 N/A Serum-1 5 / Day 1 125h
03	N/A	6 / Day 1 0 1667h	833790 95	2213643 355	0 376660	5	242	45	05104620000214	AA97220-01 05104620000214 03 N/A Serum-1 6 / Day 1 1667h
03	N/A	7 / Day 1 0 25h	753840 857	2049551 408	0 367808	5	237	46	05104620000215	AA97220-01 05104620000215 03 N/A Serum-1 7 / Day 1 25h
03	N/A	7 / Day 1 0 25h	801592 585	1821791 831	0 440002	5	283	47	05104620000231	AA97220-01 05104620000231 03 N/A Serum-1 7 / Day 1 25h
03	N/A	8 / Day 1 0 333h	893205 882	2345179 611	0 380869	5	245	49	05104620000216	AA97220-01 05104620000216 03 N/A Serum-1 8 / Day 1 333h
03	N/A	8 / Day 1 0 333h	851294 668	1960200 06	0 434290	5	279	48	05104620000232	AA97220-01 05104620000232 03 N/A Serum-1 8 / Day 1 333h
03	N/A	9 / Day 1 0 5h	677305 273	1791629 976	0 378039	5	243	52	05104620000217	AA97220-01 05104620000217 03 N/A Serum-1 9 / Day 1 5h
03	N/A	9 / Day 1 0 5h	808806 067	1897809 637	0 426179	5	274	50	05104620000233	AA97220-01 05104620000233 03 N/A Serum-1 9 / Day 1 5h
03	N/A	10 / Day 1 0 75h	656391 787	1711213 047	0 383583	5	247	54	05104620000218	AA97220-01 05104620000218 03 N/A Serum-1 10 / Day 1 75h
03	N/A	10 / Day 1 0 75h	896274 246	2085969 733	0 429668	5	276	53	05104620000234	AA97220-01 05104620000234 03 N/A Serum-1 10 / Day 1 75h
03	N/A	11 / Day 1 1h	701189 3	1820832 417	0 385093	5	248	56	05104620000219	AA97220-01 05104620000219 03 N/A Serum-1 11 / Day 1 1h
03	N/A	11 / Day 1 1h	742883 619	1723057 95	0 431143	5	277	55	05104620000235	AA97220-01 05104620000235 03 N/A Serum-1 11 / Day 1 1h
03	N/A	12 / Day 1 1 25h	623350 559	1683122 281	0 370354	5	238	57	05104620000220	AA97220-01 05104620000220 03 N/A Serum-1 12 / Day 1 1 25h
03	N/A	12 / Day 1 1 25h	719019 282	1659762 87	0 433206	5	279	58	05104620000236	AA97220-01 05104620000236 03 N/A Serum-1 12 / Day 1 1 25h
03	N/A	13 / Day 1 1 5h	796425 913	2115274 622	0 376512	5	242	61	05104620000221	AA97220-01 05104620000221 03 N/A Serum-1 13 / Day 1 1 5h
03	N/A	13 / Day 1 1 5h	781831 9	1816789 001	0 430337	5	277	60	05104620000237	AA97220-01 05104620000237 03 N/A Serum-1 13 / Day 1 1 5h
03	N/A	14 / Day 1 2h	817747 148	2232525 059	0 366288	5	236	63	05104620000222	AA97220-01 05104620000222 03 N/A Serum-1 14 / Day 1 2h
03	N/A	14 / Day 1 2h	866687 254	2085675 948	0 415543	5	267	62	05104620000238	AA97220-01 05104620000238 03 N/A Serum-1 14 / Day 1 2h
03	N/A	15 / Day 1 2 5h	680590 673	1831760 993	0 371550	5	239	65	05104620000223	AA97220-01 05104620000223 03 N/A Serum-1 15 / Day 1 2 5h
03	N/A	15 / Day 1 2 5h	713252 85	1674134 288	0 426043	5	274	64	05104620000239	AA97220-01 05104620000239 03 N/A Serum-1 15 / Day 1 2 5h
03	N/A	16 / Day 1 3h	602362 909	1658034 072	0 363299	5	234	68	05104620000224	AA97220-01 05104620000224 03 N/A Serum-1 16 / Day 1 3h
03	N/A	16 / Day 1 3h	663666 712	1645144 562	0 403409	5	260	66	05104620000240	AA97220-01 05104620000240 03 N/A Serum-1 16 / Day 1 3h
05	N/A	1 / Day 1 - 0 0333h	673412 183	1982443 063	0 339688	5	218	21	05104620000369	AA97220-01 05104620000369 05 N/A Serum-1 1 / Day 1 - 0333h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
05	N/A	2 / Day 1 0h	669336 708	2064691 796	0 324182	5	208	22	05104620000370	AA97220-01 05104620000370 05 N/A Serum-1 2 / Day 1 0h
05	N/A	3 / Day 1 0 05h	675201 895	2090383 204	0 323004	5	208	23	05104620000371	AA97220-01 05104620000371 05 N/A Serum-1 3 / Day 1 05h
05	N/A	4 / Day 1 0 0833h	694274 085	2105583 004	0 329730	5	212	24	05104620000372	AA97220-01 05104620000372 05 N/A Serum-1 4 / Day 1 0833h
05	N/A	5 / Day 1 0 125h	737702 656	2197528 592	0 335696	5	216	25	05104620000373	AA97220-01 05104620000373 05 N/A Serum-1 5 / Day 1 125h
05	N/A	6 / Day 1 0 1667h	846283 77	2100775 521	0 402844	5	259	26	05104620000374	AA97220-01 05104620000374 05 N/A Serum-1 6 / Day 1 1667h
05	N/A	7 / Day 1 0 25h	710774 092	2136303 618	0 332712	5	214	28	05104620000375	AA97220-01 05104620000375 05 N/A Serum-1 7 / Day 1 25h
05	N/A	8 / Day 1 0 333h	688690 055	1967659 62	0 350005	5	225	29	05104620000376	AA97220-01 05104620000376 05 N/A Serum-1 8 / Day 1 333h
05	N/A	9 / Day 1 0 5h	665899 913	1925279 363	0 345872	5	222	30	05104620000377	AA97220-01 05104620000377 05 N/A Serum-1 9 / Day 1 5h
05	N/A	10 / Day 1 0 75h	643512 093	1896736 523	0 339273	5	218	31	05104620000378	AA97220-01 05104620000378 05 N/A Serum-1 10 / Day 1 75h
05	N/A	11 / Day 1 1h	596696 832	1824855 353	0 326983	5	210	32	05104620000379	AA97220-01 05104620000379 05 N/A Serum-1 11 / Day 1 1h
05	N/A	12 / Day 1 1 25h	558753 081	1744477 261	0 320298	5	206	33	05104620000380	AA97220-01 05104620000380 05 N/A Serum-1 12 / Day 1 1 25h
10	N/A	1 / Day 1 - 0 0333h	738009 12	1498460 657	0 492512	5	317	69	05104620000721	AA97220-01 05104620000721 10 N/A Serum-1 1 / Day 1 - 0333h
10	N/A	1 / Day 1 - 0 0333h	622396 753	1603693 812	0 388102	5	250	70	05104620000737	AA97220-01 05104620000737 10 N/A Serum-1 1 / Day 1 - 0333h
10	N/A	2 / Day 1 0h	912678 625	1871692 159	0 487622	5	314	71	05104620000722	AA97220-01 05104620000722 10 N/A Serum-1 2 / Day 1 0h
10	N/A	2 / Day 1 0h	785084 33	1955914 816	0 401390	5	258	72	05104620000738	AA97220-01 05104620000738 10 N/A Serum-1 2 / Day 1 0h
10	N/A	3 / Day 1 0 05h	896334 818	1826883 786	0 490636	5	316	74	05104620000723	AA97220-01 05104620000723 10 N/A Serum-1 3 / Day 1 05h
10	N/A	3 / Day 1 0 05h	830607 497	2166807 398	0 383332	5	247	73	05104620000739	AA97220-01 05104620000739 10 N/A Serum-1 3 / Day 1 05h
10	N/A	4 / Day 1 0 0833h	987119 85	2018802 207	0 488963	5	315	77	05104620000724	AA97220-01 05104620000724 10 N/A Serum-1 4 / Day 1 0833h
10	N/A	4 / Day 1 0 0833h	840552 463	2092177 323	0 401760	5	258	76	05104620000740	AA97220-01 05104620000740 10 N/A Serum-1 4 / Day 1 0833h
10	N/A	5 / Day 1 0 125h	839719 375	1701517 386	0 493512	5	318	78	05104620000725	AA97220-01 05104620000725 10 N/A Serum-1 5 / Day 1 125h
10	N/A	5 / Day 1 0 125h	726631 647	1823173 955	0 398553	5	256	79	05104620000741	AA97220-01 05104620000741 10 N/A Serum-1 5 / Day 1 125h
10	N/A	6 / Day 1 0 1667h	811814 985	1720843 751	0 471754	5	304	81	05104620000726	AA97220-01 05104620000726 10 N/A Serum-1 6 / Day 1 1667h
10	N/A	6 / Day 1 0 1667h	670884 502	1596242 575	0 420290	5	270	80	05104620000742	AA97220-01 05104620000742 10 N/A Serum-1 6 / Day 1 1667h
10	N/A	7 / Day 1 0 25h	868476 604	1787550 343	0 485847	5	313	82	05104620000727	AA97220-01 05104620000727 10 N/A Serum-1 7 / Day 1 25h
10	N/A	7 / Day 1 0 25h	728924 845	1856553 179	0 392623	5	253	84	05104620000743	AA97220-01 05104620000743 10 N/A Serum-1 7 / Day 1 25h
10	N/A	8 / Day 1 0 333h	916012 339	1905692 544	0 480672	5	309	85	05104620000728	AA97220-01 05104620000728 10 N/A Serum-1 8 / Day 1 333h
10	N/A	8 / Day 1 0 333h	765668 098	1921994 826	0 398372	5	256	86	05104620000744	AA97220-01 05104620000744 10 N/A Serum-1 8 / Day 1 333h
10	N/A	9 / Day 1 0 5h	917278 173	1869299 176	0 490707	5	316	88	05104620000729	AA97220-01 05104620000729 10 N/A Serum-1 9 / Day 1 5h
10	N/A	9 / Day 1 0 5h	849416 325	2190441 809	0 387783	5	249	87	05104620000745	AA97220-01 05104620000745 10 N/A Serum-1 9 / Day 1 5h
10	N/A	10 / Day 1 0 75h	1036633 708	2161719 431	0 479541	5	309	90	05104620000730	AA97220-01 05104620000730 10 N/A Serum-1 10 / Day 1 75h
10	N/A	10 / Day 1 0 75h	803648 267	2018369 816	0 398167	5	256	89	05104620000746	AA97220-01 05104620000746 10 N/A Serum-1 10 / Day 1 75h

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)
AAR - Concentration Found is Greater than 200 (Highest Standard)

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 30
Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		1465 168	1776162 659	0 000825	-0 0810		-0 0659	-32 5
9	0 00		1743 967	1659438 711	0 001051	-0 0508			
10	1 00	1 00000	19467 192	2209879 429	0 008809	0 985	-1 5		
11	2 00	0 250000	35823 023	2145163 181	0 016699	2 04	2 0		
12	4 00	0 0625000	61015 81	1855579 094	0 032882	4 20	5 0		
13	8 00	0 0156250	127332 817	2135084 882	0 059638	7 77	-2 9		
14	16 0	0 00390625	212889 867	1868220 321	0 113953	15 0	-6 3		
15	40 0	0 000625000	551451 317	1867049 374	0 295360	39 3	-1 8		
16	80 0	0 000156250	1115495 396	1855603 204	0 601150	80 1	0 1		
17	160	0 0000390625	2650035 21	2140503 318	1 238043	165	3 1		
18	200	0 0000250000	2841682 153	1858831 784	1 528746	204	2 0		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:

Slope = 0 00748808478

Intercept = 0 00143130183

R-Squared = 0 9984

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 30
Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	2994088 554	1971079 477	1 519010	1	203		203		0 9
2	0 00	2827845 178	1852354 34	1 526622	1	204				
3	0 00	2929516 367	1917277 287	1 527957	1	204				
4	0 00	3359495 789	2204538 301	1 523900	1	203				
5	0 00	3282045 459	2179413 161	1 505931	1	201				
91	0 00	2572401 749	1713320 414	1 501413	1	200				
92	0 00	2987931 633	1948249 951	1 533649	1	205				
30	3 00	39716 547	1683809 132	0 023587	1	2 96	-1 3	2 90	-3 3	2 9
63	3 00	35206 675	1550255 105	0 022710	1	2 84	-5 3			
41	37 5	430046 431	1526085 201	0 281797	1	37 4	-0 3	36 1	-3 7	5 3
74	37 5	453265 346	1734851 484	0 261270	1	34 7	-7 5			
52	150	1756915 682	1668593 014	1 052932	1	140	-6 7	139	-7 3	1 0
89	150	2120669 315	2045588 521	1 036704	1	138	-8 0			

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)
AAR - Concentration Found is Greater than 200 (Highest Standard)

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 30
Serum, Concentration of Cotinine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
13	N/A	1 / Day 1 -0 0333h	1504257 283	1853194 707	0 811710	1	108	23	05104620000977	AA97220-01 05104620000977 13 N/A Serum-1 1 / Day 1 - 0333h
13	N/A	1 / Day 1 -0 0333h	1466043 349	2036289 718	0 719958	1	96 0	20	05104620000993	AA97220-01 05104620000993 13 N/A Serum-1 1 / Day 1 - 0333h
13	N/A	1 / Day 1 -0 0333h	3260866 877	2162074 198	*1 508212	1	*AAR>(200)	22	05104620001009	AA97220-01 05104620001009 13 N/A Serum-1 1 / Day 1 - 0333h
13	N/A	1 / Day 1 -0 0333h	931958 638	1782958 788	0 522703	1	69 6	21	05104620001025	AA97220-01 05104620001025 13 N/A Serum-1 1 / Day 1 - 0333h
13	N/A	2 / Day 1 0h	1432183 595	2002953 545	0 715036	1	95 3	26	05104620000978	AA97220-01 05104620000978 13 N/A Serum-1 2 / Day 1 0h
13	N/A	2 / Day 1 0h	1494752 353	1909584 836	0 782763	1	104	25	05104620000994	AA97220-01 05104620000994 13 N/A Serum-1 2 / Day 1 0h
13	N/A	2 / Day 1 0h	2960814 668	1871495 459	*1 582058	1	*AAR>(200)	24	05104620001010	AA97220-01 05104620001010 13 N/A Serum-1 2 / Day 1 0h
13	N/A	2 / Day 1 0h	838110 213	1637299 756	0 511886	1	68 2	27	05104620001026	AA97220-01 05104620001026 13 N/A Serum-1 2 / Day 1 0h
13	N/A	3 / Day 1 0 05h	1501391 612	1757467 853	0 854293	1	114	29	05104620000979	AA97220-01 05104620000979 13 N/A Serum-1 3 / Day 1 05h
13	N/A	3 / Day 1 0 05h	1547713 954	2050333 543	0 754860	1	101	32	05104620000995	AA97220-01 05104620000995 13 N/A Serum-1 3 / Day 1 05h
13	N/A	3 / Day 1 0 05h	2481520 283	1617410 413	*1 534255	1	*AAR>(200)	31	05104620001011	AA97220-01 05104620001011 13 N/A Serum-1 3 / Day 1 05h
13	N/A	3 / Day 1 0 05h	966060 942	1779429 196	0 542905	1	72 3	28	05104620001027	AA97220-01 05104620001027 13 N/A Serum-1 3 / Day 1 05h
13	N/A	4 / Day 1 0 0833h	1423563 891	1646711 25	0 864489	1	115	33	05104620000980	AA97220-01 05104620000980 13 N/A Serum-1 4 / Day 1 0833h
13	N/A	4 / Day 1 0 0833h	1089079 804	1429123 078	0 762062	1	102	35	05104620000996	AA97220-01 05104620000996 13 N/A Serum-1 4 / Day 1 0833h
13	N/A	4 / Day 1 0 0833h	2616640 187	1727583 651	*1 514624	1	*AAR>(200)	36	05104620001012	AA97220-01 05104620001012 13 N/A Serum-1 4 / Day 1 0833h
13	N/A	4 / Day 1 0 0833h	960027 496	1802512 037	0 532605	1	70 9	34	05104620001028	AA97220-01 05104620001028 13 N/A Serum-1 4 / Day 1 0833h
13	N/A	5 / Day 1 0 125h	1310414 775	1561489 037	0 839208	1	112	38	05104620000981	AA97220-01 05104620000981 13 N/A Serum-1 5 / Day 1 125h
13	N/A	5 / Day 1 0 125h	1277705 743	1753504 271	0 728658	1	97 1	39	05104620000997	AA97220-01 05104620000997 13 N/A Serum-1 5 / Day 1 125h
13	N/A	5 / Day 1 0 125h	2957425 729	1992236 221	1 484475	1	198	37	05104620001013	AA97220-01 05104620001013 13 N/A Serum-1 5 / Day 1 125h
13	N/A	5 / Day 1 0 125h	966525 702	1817711 035	0 531727	1	70 8	40	05104620001029	AA97220-01 05104620001029 13 N/A Serum-1 5 / Day 1 125h
13	N/A	6 / Day 1 0 1667h	1696165 082	1958914 221	0 865870	1	115	42	05104620000982	AA97220-01 05104620000982 13 N/A Serum-1 6 / Day 1 1667h
13	N/A	6 / Day 1 0 1667h	1194562 218	1671429 705	0 714695	1	95 3	44	05104620000998	AA97220-01 05104620000998 13 N/A Serum-1 6 / Day 1 1667h
13	N/A	6 / Day 1 0 1667h	2405456 149	1575010 735	*1 527263	1	*AAR>(200)	45	05104620001014	AA97220-01 05104620001014 13 N/A Serum-1 6 / Day 1 1667h
13	N/A	6 / Day 1 0 1667h	0	0	*N/A	1	*BLQ<(1 00)	43	05104620001030	AA97220-01 05104620001030 13 N/A Serum-1 6 / Day 1 1667h
13	N/A	7 / Day 1 0 25h	1587889 833	1879034 569	0 845056	1	113	48	05104620000983	AA97220-01 05104620000983 13 N/A Serum-1 7 / Day 1 25h
13	N/A	7 / Day 1 0 25h	1354257 203	1794869 789	0 754516	1	101	49	05104620000999	AA97220-01 05104620000999 13 N/A Serum-1 7 / Day 1 25h
13	N/A	7 / Day 1 0 25h	2525764 978	1792175 544	1 409329	1	188	47	05104620001015	AA97220-01 05104620001015 13 N/A Serum-1 7 / Day 1 25h
13	N/A	7 / Day 1 0 25h	865707 172	1599913 761	0 541096	1	72 1	46	05104620001031	AA97220-01 05104620001031 13 N/A Serum-1 7 / Day 1 25h
13	N/A	8 / Day 1 0 333h	1222986 701	1585521 725	0 771347	1	103	53	05104620000984	AA97220-01 05104620000984 13 N/A Serum-1 8 / Day 1 333h
13	N/A	8 / Day 1 0 333h	1523567 748	1988592 556	0 766154	1	102	51	05104620001000	AA97220-01 05104620001000 13 N/A Serum-1 8 / Day 1 333h
13	N/A	8 / Day 1 0 333h	2465012 223	1664200 891	1 481199	1	198	54	05104620001016	AA97220-01 05104620001016 13 N/A Serum-1 8 / Day 1 333h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
13	N/A	8 / Day 1 0 333h	1170960 831	2016769 045	0 580612	1	77 3	50	05104620001032	AA97220-01 05104620001032 13 N/A Serum-1 8 / Day 1 333h
13	N/A	9 / Day 1 0 5h	1445260 7	1729071 75	0 835859	1	111	57	05104620000985	AA97220-01 05104620000985 13 N/A Serum-1 9 / Day 1 5h
13	N/A	9 / Day 1 0 5h	1545808 246	1845744 05	0 837499	1	112	58	05104620001001	AA97220-01 05104620001001 13 N/A Serum-1 9 / Day 1 5h
13	N/A	9 / Day 1 0 5h	2513785 558	1716797 705	1 464229	1	195	56	05104620001017	AA97220-01 05104620001017 13 N/A Serum-1 9 / Day 1 5h
13	N/A	9 / Day 1 0 5h	974029 105	1533299 792	0 635250	1	84 6	55	05104620001033	AA97220-01 05104620001033 13 N/A Serum-1 9 / Day 1 5h
13	N/A	10 / Day 1 0 75h	1360141 754	1628670 667	0 835124	1	111	59	05104620000986	AA97220-01 05104620000986 13 N/A Serum-1 10 / Day 1 75h
13	N/A	10 / Day 1 0 75h	1469136 506	1699550 926	0 864426	1	115	62	05104620001002	AA97220-01 05104620001002 13 N/A Serum-1 10 / Day 1 75h
13	N/A	10 / Day 1 0 75h	2604684 801	1789827 243	1 455272	1	194	61	05104620001018	AA97220-01 05104620001018 13 N/A Serum-1 10 / Day 1 75h
13	N/A	10 / Day 1 0 75h	926739 047	1549932 639	0 597922	1	79 7	60	05104620001034	AA97220-01 05104620001034 13 N/A Serum-1 10 / Day 1 75h
13	N/A	11 / Day 1 1h	1337577 625	1684086 243	0 794245	1	106	67	05104620000987	AA97220-01 05104620000987 13 N/A Serum-1 11 / Day 1 1h
13	N/A	11 / Day 1 1h	1418040 917	1671709 43	0 848258	1	113	65	05104620001003	AA97220-01 05104620001003 13 N/A Serum-1 11 / Day 1 1h
13	N/A	11 / Day 1 1h	2450611 348	1688397 868	1 451442	1	194	66	05104620001019	AA97220-01 05104620001019 13 N/A Serum-1 11 / Day 1 1h
13	N/A	11 / Day 1 1h	939825 852	1517682 664	0 619251	1	82 5	64	05104620001035	AA97220-01 05104620001035 13 N/A Serum-1 11 / Day 1 1h
13	N/A	12 / Day 1 1 25h	1256487 533	1500177 318	0 837559	1	112	69	05104620000988	AA97220-01 05104620000988 13 N/A Serum-1 12 / Day 1 1 25h
13	N/A	12 / Day 1 1 25h	1361076 016	1631902 776	0 834042	1	111	71	05104620001004	AA97220-01 05104620001004 13 N/A Serum-1 12 / Day 1 1 25h
13	N/A	12 / Day 1 1 25h	2435110 802	1712355 603	1 422082	1	190	70	05104620001020	AA97220-01 05104620001020 13 N/A Serum-1 12 / Day 1 1 25h
13	N/A	12 / Day 1 1 25h	893852 374	1558794 857	0 573425	1	76 4	68	05104620001036	AA97220-01 05104620001036 13 N/A Serum-1 12 / Day 1 1 25h
13	N/A	13 / Day 1 1 5h	1742836 063	2101590 44	0 829294	1	111	73	05104620000989	AA97220-01 05104620000989 13 N/A Serum-1 13 / Day 1 1 5h
13	N/A	13 / Day 1 1 5h	1344310 714	1664445 002	0 807663	1	108	76	05104620001005	AA97220-01 05104620001005 13 N/A Serum-1 13 / Day 1 1 5h
13	N/A	13 / Day 1 1 5h	2535810 118	1826458 252	1 388376	1	185	72	05104620001021	AA97220-01 05104620001021 13 N/A Serum-1 13 / Day 1 1 5h
13	N/A	13 / Day 1 1 5h	1217550 087	2114002 472	0 575945	1	76 7	75	05104620001037	AA97220-01 05104620001037 13 N/A Serum-1 13 / Day 1 1 5h
13	N/A	14 / Day 1 2h	1095665 324	1487423 046	0 736620	1	98 2	78	05104620000990	AA97220-01 05104620000990 13 N/A Serum-1 14 / Day 1 2h
13	N/A	14 / Day 1 2h	1429045 453	1891343 875	0 755571	1	101	79	05104620001006	AA97220-01 05104620001006 13 N/A Serum-1 14 / Day 1 2h
13	N/A	14 / Day 1 2h	2881559 203	2148499 171	1 341196	1	179	77	05104620001022	AA97220-01 05104620001022 13 N/A Serum-1 14 / Day 1 2h
13	N/A	14 / Day 1 2h	1151230 288	1938137 558	0 593988	1	79 1	80	05104620001038	AA97220-01 05104620001038 13 N/A Serum-1 14 / Day 1 2h
13	N/A	15 / Day 1 2 5h	1394424 525	1890083 403	0 737758	1	98 3	83	05104620000991	AA97220-01 05104620000991 13 N/A Serum-1 15 / Day 1 2 5h
13	N/A	15 / Day 1 2 5h	1262388 567	1653486 84	0 763471	1	102	82	05104620001007	AA97220-01 05104620001007 13 N/A Serum-1 15 / Day 1 2 5h
13	N/A	15 / Day 1 2 5h	2547538 698	1962422 85	1 298160	1	173	81	05104620001023	AA97220-01 05104620001023 13 N/A Serum-1 15 / Day 1 2 5h
13	N/A	15 / Day 1 2 5h	1136805 847	2059187 019	0 552065	1	73 5	85	05104620001039	AA97220-01 05104620001039 13 N/A Serum-1 15 / Day 1 2 5h
13	N/A	16 / Day 1 3h	1251007 425	1736933 883	0 720239	1	96 0	86	05104620000992	AA97220-01 05104620000992 13 N/A Serum-1 16 / Day 1 3h
13	N/A	16 / Day 1 3h	1222053 154	1709409 904	0 714898	1	95 3	84	05104620001008	AA97220-01 05104620001008 13 N/A Serum-1 16 / Day 1 3h
13	N/A	16 / Day 1 3h	2469007 196	2023806 972	1 219982	1	163	87	05104620001024	AA97220-01 05104620001024 13 N/A Serum-1 16 / Day 1 3h
13	N/A	16 / Day 1 3h	895653 627	1697295 613	0 527695	1	70 3	88	05104620001040	AA97220-01 05104620001040 13 N/A Serum-1 16 / Day 1 3h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1.00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

* - Sample Rejected

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 31
 Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		0	1763693 052	0 000000	-0 0447		-0 0447	0 0
9	0 00		0	2001010 445	0 000000	-0 0447			
10	1 00	1 00000	12889 588	1684959 958	0 007650	0 970	-3 0		
11	2 00	0 250000	29396 844	1824345 288	0 016114	2 09	4 5		
12	4 00	0 0625000	58022 67	1835584 287	0 031610	4 15	3 8		
13	8 00	0 0156250	113934 815	1892103 222	0 060216	7 94	-0 8		
14	16 0	0 00390625	210408 206	1764965 258	0 119214	15 8	-1 3		
15	40 0	0 000625000	516329 462	1716961 895	0 300723	39 8	-0 5		
16	80 0	0 000156250	1099115 914	1854680 875	0 592617	78 6	-1 8		
17	160	0 0000390625	2059346 362	1722668 218	1 195440	158	-1 3		
18	200	0 0000250000	2275955 157	1508105 85	1 509148	200	0 0		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:

Slope = 0 00754013477

Intercept = 0 000336911067

R-Squared = 0 9992

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 31
 Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	2419631 983	1601359 988	1 510986	1	200		198		1 1
2	0 00	2701763 433	1812864 739	1 490328	1	198				
3	0 00	2422361 449	1642405 237	1 474887	1	196				
4	0 00	2461696 548	1625501 219	1 514423	1	201				
5	0 00	2464594 613	1677615 786	1 469106	1	195				
93	0 00	2221196 409	1478704 502	1 502123	1	199				
94	0 00	2242979 052	1510541 464	1 484884	1	197				
37	3 00	38529 344	1672317 839	0 023039	1	3 01	0 3	2 90	-3 3	5 4
68	3 00	36919 829	1728181 579	0 021363	1	2 79	-7 0			
45	37 5	384894 789	1408520 523	0 273262	1	36 2	-3 5	36 0	-4 0	1 0
74	37 5	500586 232	1857870 375	0 269441	1	35 7	-4 8			
28	150	344591 653	1586729 279	0 217171	5	144	-4 0	140	-6 7	3 3
61	150	315207 575	1544638 108	0 204066	5	135	-10 0			
82	150	408464 752	1919314 49	0 212818	5	141	-6 0			
54	150	1343214 012	1256527 111	1 068989	1	142	-5 3	145	-3 3	2 9
91	150	1635006 377	1461363 211	1 118823	1	148	-1 3			

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 31
Serum, Concentration of Cotinine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
16	N/A	1 / Day 1 - 0 0333h	539540 933	1673458 184	0 322411	5	214	75	05104620001201	AA97220-01 05104620001201 16 N/A Serum-1 1 / Day 1 - 0333h
16	N/A	2 / Day 1 0h	601203 845	1882781 908	0 319317	5	212	76	05104620001202	AA97220-01 05104620001202 16 N/A Serum-1 2 / Day 1 0h
16	N/A	3 / Day 1 0 05h	551786 732	1717733 692	0 321229	5	213	77	05104620001203	AA97220-01 05104620001203 16 N/A Serum-1 3 / Day 1 05h
16	N/A	4 / Day 1 0 0833h	569180 452	1779766 451	0 319806	5	212	78	05104620001204	AA97220-01 05104620001204 16 N/A Serum-1 4 / Day 1 0833h
16	N/A	5 / Day 1 0 125h	548691 694	1763532 243	0 311132	5	206	79	05104620001205	AA97220-01 05104620001205 16 N/A Serum-1 5 / Day 1 125h
16	N/A	6 / Day 1 0 1667h	567227 351	1838271 422	0 308566	5	204	80	05104620001206	AA97220-01 05104620001206 16 N/A Serum-1 6 / Day 1 1667h
16	N/A	7 / Day 1 0 25h	509728 195	1668931 529	0 305422	5	202	81	05104620001207	AA97220-01 05104620001207 16 N/A Serum-1 7 / Day 1 25h
16	N/A	8 / Day 1 0 333h	452658 056	1519827 977	0 297835	5	197	83	05104620001208	AA97220-01 05104620001208 16 N/A Serum-1 8 / Day 1 333h
16	N/A	9 / Day 1 0 5h	455745 496	1435359 37	0 317513	5	210	84	05104620001209	AA97220-01 05104620001209 16 N/A Serum-1 9 / Day 1 5h
16	N/A	10 / Day 1 0 75h	515021 414	1505535 722	0 342085	5	227	85	05104620001210	AA97220-01 05104620001210 16 N/A Serum-1 10 / Day 1 75h
16	N/A	11 / Day 1 1h	485859 226	1437551 45	0 337977	5	224	86	05104620001211	AA97220-01 05104620001211 16 N/A Serum-1 11 / Day 1 1h
16	N/A	12 / Day 1 1 25h	475539 492	1436204 416	0 331109	5	219	87	05104620001212	AA97220-01 05104620001212 16 N/A Serum-1 12 / Day 1 1 25h
16	N/A	13 / Day 1 1 5h	487711 667	1555579 899	0 313524	5	208	88	05104620001213	AA97220-01 05104620001213 16 N/A Serum-1 13 / Day 1 1 5h
16	N/A	14 / Day 1 2h	508989 469	1551473 037	0 328069	5	217	89	05104620001214	AA97220-01 05104620001214 16 N/A Serum-1 14 / Day 1 2h
16	N/A	15 / Day 1 2 5h	467640 084	1431408 327	0 326699	5	216	90	05104620001215	AA97220-01 05104620001215 16 N/A Serum-1 15 / Day 1 2 5h
17	N/A	1 / Day 1 - 0 0333h	697467 885	1908520 221	0 365450	5	242	22	05104620001297	AA97220-01 05104620001297 17 N/A Serum-1 1 / Day 1 - 0333h
17	N/A	1 / Day 1 - 0 0333h	592451 684	1663492 129	0 356149	5	236	21	05104620001313	AA97220-01 05104620001313 17 N/A Serum-1 1 / Day 1 - 0333h
17	N/A	1 / Day 1 - 0 0333h	652688 31	2118276 642	0 308122	5	204	20	05104620001345	AA97220-01 05104620001345 17 N/A Serum-1 1 / Day 1 - 0333h
17	N/A	2 / Day 1 0h	712919 923	1805411 453	0 394879	5	262	23	05104620001298	AA97220-01 05104620001298 17 N/A Serum-1 2 / Day 1 0h
17	N/A	2 / Day 1 0h	642808 666	1798667 216	0 357381	5	237	25	05104620001314	AA97220-01 05104620001314 17 N/A Serum-1 2 / Day 1 0h
17	N/A	2 / Day 1 0h	598804 225	1807699 516	0 331252	5	219	24	05104620001346	AA97220-01 05104620001346 17 N/A Serum-1 2 / Day 1 0h
17	N/A	3 / Day 1 0 05h	675576 457	1666403 366	0 405410	5	269	27	05104620001299	AA97220-01 05104620001299 17 N/A Serum-1 3 / Day 1 05h
17	N/A	3 / Day 1 0 05h	747516 091	2039893 181	0 366449	5	243	26	05104620001315	AA97220-01 05104620001315 17 N/A Serum-1 3 / Day 1 05h
17	N/A	3 / Day 1 0 05h	513456 12	1615206 434	0 317889	5	211	29	05104620001347	AA97220-01 05104620001347 17 N/A Serum-1 3 / Day 1 05h
17	N/A	4 / Day 1 0 0833h	704185 925	1784233 922	0 394671	5	261	32	05104620001300	AA97220-01 05104620001300 17 N/A Serum-1 4 / Day 1 0833h
17	N/A	4 / Day 1 0 0833h	581225 572	1707077 716	0 340480	5	226	30	05104620001316	AA97220-01 05104620001316 17 N/A Serum-1 4 / Day 1 0833h
17	N/A	4 / Day 1 0 0833h	546600 612	1694548 671	0 322564	5	214	31	05104620001348	AA97220-01 05104620001348 17 N/A Serum-1 4 / Day 1 0833h
17	N/A	5 / Day 1 0 125h	699823 773	1800257 888	0 388735	5	258	35	05104620001301	AA97220-01 05104620001301 17 N/A Serum-1 5 / Day 1 125h
17	N/A	5 / Day 1 0 125h	615234 128	1736609 219	0 354273	5	235	34	05104620001317	AA97220-01 05104620001317 17 N/A Serum-1 5 / Day 1 125h
17	N/A	5 / Day 1 0 125h	562227 855	1748559 375	0 321538	5	213	33	05104620001349	AA97220-01 05104620001349 17 N/A Serum-1 5 / Day 1 125h
17	N/A	6 / Day 1 0 1667h	759395 089	1833905 606	0 414086	5	274	39	05104620001302	AA97220-01 05104620001302 17 N/A Serum-1 6 / Day 1 1667h
17	N/A	6 / Day 1 0 1667h	575428 36	1655822 484	0 347518	5	230	38	05104620001318	AA97220-01 05104620001318 17 N/A Serum-1 6 / Day 1 1667h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
17	N/A	6 / Day 1 0 1667h	566937 275	1705073 619	0 332500	5	220	36	05104620001350	AA97220-01 05104620001350 17 N/A Serum-1 6 / Day 1 1667h
17	N/A	7 / Day 1 0 25h	701997 605	1806031 257	0 388696	5	258	41	05104620001303	AA97220-01 05104620001303 17 N/A Serum-1 7 / Day 1 25h
17	N/A	7 / Day 1 0 25h	704149 346	1974765 642	0 356574	5	236	42	05104620001319	AA97220-01 05104620001319 17 N/A Serum-1 7 / Day 1 25h
17	N/A	7 / Day 1 0 25h	550567 646	1696222 2	0 324585	5	215	40	05104620001351	AA97220-01 05104620001351 17 N/A Serum-1 7 / Day 1 25h
17	N/A	8 / Day 1 0 333h	675132 976	1735539 339	0 389005	5	258	43	05104620001304	AA97220-01 05104620001304 17 N/A Serum-1 8 / Day 1 333h
17	N/A	8 / Day 1 0 333h	515875 793	1590634 634	0 324321	5	215	46	05104620001320	AA97220-01 05104620001320 17 N/A Serum-1 8 / Day 1 333h
17	N/A	8 / Day 1 0 333h	572818 675	1655025 166	0 346109	5	229	44	05104620001352	AA97220-01 05104620001352 17 N/A Serum-1 8 / Day 1 333h
17	N/A	9 / Day 1 0 5h	600653 994	1544302 132	0 388948	5	258	49	05104620001305	AA97220-01 05104620001305 17 N/A Serum-1 9 / Day 1 5h
17	N/A	9 / Day 1 0 5h	639861 597	1760583 69	0 363437	5	241	47	05104620001321	AA97220-01 05104620001321 17 N/A Serum-1 9 / Day 1 5h
17	N/A	9 / Day 1 0 5h	526287 802	1571416 193	0 334913	5	222	48	05104620001353	AA97220-01 05104620001353 17 N/A Serum-1 9 / Day 1 5h
17	N/A	10 / Day 1 0 75h	561566 498	1487808 401	0 377445	5	250	51	05104620001306	AA97220-01 05104620001306 17 N/A Serum-1 10 / Day 1 75h
17	N/A	10 / Day 1 0 75h	569381 284	1568953 351	0 362905	5	240	52	05104620001322	AA97220-01 05104620001322 17 N/A Serum-1 10 / Day 1 75h
17	N/A	10 / Day 1 0 75h	495334 707	1390066 887	0 356339	5	236	50	05104620001354	AA97220-01 05104620001354 17 N/A Serum-1 10 / Day 1 75h
17	N/A	11 / Day 1 1h	561171 535	1518055 368	0 369665	5	245	53	05104620001307	AA97220-01 05104620001307 17 N/A Serum-1 11 / Day 1 1h
17	N/A	11 / Day 1 1h	791598 488	2146790 76	0 368736	5	244	55	05104620001323	AA97220-01 05104620001323 17 N/A Serum-1 11 / Day 1 1h
17	N/A	11 / Day 1 1h	499033 461	1515566 931	0 329272	5	218	56	05104620001355	AA97220-01 05104620001355 17 N/A Serum-1 11 / Day 1 1h
17	N/A	12 / Day 1 1 25h	488233 609	1363601 171	0 358047	5	237	57	05104620001308	AA97220-01 05104620001308 17 N/A Serum-1 12 / Day 1 1 25h
17	N/A	12 / Day 1 1 25h	492226 767	1440694 405	0 341659	5	226	59	05104620001324	AA97220-01 05104620001324 17 N/A Serum-1 12 / Day 1 1 25h
17	N/A	12 / Day 1 1 25h	421914 899	1359790 219	0 310279	5	206	58	05104620001356	AA97220-01 05104620001356 17 N/A Serum-1 12 / Day 1 1 25h
17	N/A	13 / Day 1 1 5h	585529 209	1627878 737	0 359688	5	238	62	05104620001309	AA97220-01 05104620001309 17 N/A Serum-1 13 / Day 1 1 5h
17	N/A	13 / Day 1 1 5h	552902 595	1629515 139	0 339305	5	225	63	05104620001325	AA97220-01 05104620001325 17 N/A Serum-1 13 / Day 1 1 5h
17	N/A	13 / Day 1 1 5h	486076 52	1536979 015	0 316254	5	209	60	05104620001357	AA97220-01 05104620001357 17 N/A Serum-1 13 / Day 1 1 5h
17	N/A	14 / Day 1 2h	638024 249	1748607 096	0 364876	5	242	65	05104620001310	AA97220-01 05104620001310 17 N/A Serum-1 14 / Day 1 2h
17	N/A	14 / Day 1 2h	661255 42	1977938 331	0 334315	5	221	64	05104620001326	AA97220-01 05104620001326 17 N/A Serum-1 14 / Day 1 2h
17	N/A	14 / Day 1 2h	536808 698	1704016 176	0 315026	5	209	66	05104620001358	AA97220-01 05104620001358 17 N/A Serum-1 14 / Day 1 2h
17	N/A	15 / Day 1 2 5h	627396 104	1806019 231	0 347392	5	230	70	05104620001311	AA97220-01 05104620001311 17 N/A Serum-1 15 / Day 1 2 5h
17	N/A	15 / Day 1 2 5h	544664 492	1693644 762	0 321593	5	213	69	05104620001327	AA97220-01 05104620001327 17 N/A Serum-1 15 / Day 1 2 5h
17	N/A	15 / Day 1 2 5h	482824 191	1555635 637	0 310371	5	206	67	05104620001359	AA97220-01 05104620001359 17 N/A Serum-1 15 / Day 1 2 5h
17	N/A	16 / Day 1 3h	584702 454	1788043 831	0 327007	5	217	72	05104620001312	AA97220-01 05104620001312 17 N/A Serum-1 16 / Day 1 3h
17	N/A	16 / Day 1 3h	563548 958	1731700 049	0 325431	5	216	71	05104620001328	AA97220-01 05104620001328 17 N/A Serum-1 16 / Day 1 3h
17	N/A	16 / Day 1 3h	596012 485	1926369 841	0 309397	5	205	73	05104620001360	AA97220-01 05104620001360 17 N/A Serum-1 16 / Day 1 3h

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 32
 Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		0	430976 235	0 000000	-0 0776		-0 0776	0 0
9	0 00		0	426405 136	0 000000	-0 0776			
10	1 00	1 00000	29184 12	448993 973	0 064999	0 978	-2 2		
11	2 00	0 250000	58326 013	442926 519	0 131683	2 06	3 0		
12	4 00	0 0625000	123044 907	476694 395	0 258121	4 11	2 8		
13	8 00	0 0156250	217498 795	432084 137	0 503371	8 10	1 3		
14	16 0	0 00390625	452282 703	459077 298	0 985199	15 9	-0 6		
15	40 0	0 000625000	1000199 612	422682 97	2 366312	38 3	-4 3		
16	80 0	0 000156250	2256007 331	456264 068	4 944521	80 2	0 3		
17	160	0 0000390625	3727446 019	375669 194	9 922150	161	0 6		
18	200	0 0000250000	4772478 009	391306 821	12 196256	198	-1 0		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:

Slope = 0 0615922188

Intercept = 0 00478093043

R-Squared = 0 9993

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 32
 Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	5574612 999	462453 058	12 054441	1	196		197		1 3
2	0 00	5298020 991	446180 516	11 874165	1	193				
3	0 00	5385637 977	443086 982	12 154810	1	197				
4	0 00	5628407 3	466866 604	12 055708	1	196				
5	0 00	5027802 336	413400 736	12 162055	1	197				
81	0 00	3839959 45	312638 072	12 282443	1	199				
82	0 00	3743251 832	302133 265	12 389406	1	201				
32	3 00	50275 597	256531 811	0 195982	1	3 10	3 3	3 15	5 0	2 0
60	3 00	61455 995	305112 106	0 201421	1	3 19	6 3			
39	37 5	705776 142	313544 199	2 250962	1	36 5	-2 7	37 1	-1 1	2 3
67	37 5	766497 173	329431 839	2 326725	1	37 7	0 5			
26	150	490155 541	281568 915	1 740801	5	141	-6 0	143	-4 7	1 4
52	150	459993 152	256505 982	1 793304	5	145	-3 3			
73	150	494674 798	280229 848	1 765247	5	143	-4 7			
45	150	2191021 658	249276 865	8 789511	1	143	-4 7	144	-4 0	1 0
79	150	2990596 013	335145 209	8 923284	1	145	-3 3			

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 32
Serum, Concentration of Cotinine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
09	N/A	1 / Day 1 - 0 0333h	825764 939	310376 674	2 660525	5	216	78	05104620000705	AA97220-01 05104620000705 09 N/A Serum-1 1 / Day 1 - 0333h
14	N/A	1 / Day 1 - 0 0333h	1095845 561	401234 409	2 731185	5	221	21	05104620001041	AA97220-01 05104620001041 14 N/A Serum-1 1 / Day 1 - 0333h
14	N/A	1 / Day 1 - 0 0333h	957264 957	380913 039	2 513080	5	204	20	05104620001057	AA97220-01 05104620001057 14 N/A Serum-1 1 / Day 1 - 0333h
14	N/A	2 / Day 1 0h	1214916 538	433080 438	2 805291	5	227	22	05104620001042	AA97220-01 05104620001042 14 N/A Serum-1 2 / Day 1 0h
14	N/A	3 / Day 1 0 05h	980284 28	356122 628	2 752659	5	223	23	05104620001043	AA97220-01 05104620001043 14 N/A Serum-1 3 / Day 1 05h
14	N/A	4 / Day 1 0 0833h	1094004 297	411871 807	2 656177	5	215	24	05104620001044	AA97220-01 05104620001044 14 N/A Serum-1 4 / Day 1 0833h
14	N/A	4 / Day 1 0 0833h	923079 623	363058 299	2 542511	5	206	25	05104620001060	AA97220-01 05104620001060 14 N/A Serum-1 4 / Day 1 0833h
14	N/A	5 / Day 1 0 125h	1133528 52	408877 255	2 772295	5	225	27	05104620001045	AA97220-01 05104620001045 14 N/A Serum-1 5 / Day 1 125h
14	N/A	6 / Day 1 0 1667h	964863 972	355194 152	2 716441	5	220	28	05104620001046	AA97220-01 05104620001046 14 N/A Serum-1 6 / Day 1 1667h
14	N/A	7 / Day 1 0 25h	932159 732	329444 481	2 829490	5	229	29	05104620001047	AA97220-01 05104620001047 14 N/A Serum-1 7 / Day 1 25h
14	N/A	8 / Day 1 0 333h	813974 743	304903 991	2 669610	5	216	30	05104620001048	AA97220-01 05104620001048 14 N/A Serum-1 8 / Day 1 333h
14	N/A	8 / Day 1 0 333h	820663 688	326527 329	2 513308	5	204	31	05104620001064	AA97220-01 05104620001064 14 N/A Serum-1 8 / Day 1 333h
14	N/A	9 / Day 1 0 5h	707750 13	273897 804	2 583993	5	209	33	05104620001049	AA97220-01 05104620001049 14 N/A Serum-1 9 / Day 1 5h
14	N/A	10 / Day 1 0 75h	813351 598	292727 68	2 778526	5	225	35	05104620001050	AA97220-01 05104620001050 14 N/A Serum-1 10 / Day 1 75h
14	N/A	10 / Day 1 0 75h	708130 465	274931 318	2 575663	5	209	34	05104620001066	AA97220-01 05104620001066 14 N/A Serum-1 10 / Day 1 75h
14	N/A	11 / Day 1 1h	855152 409	312985 056	2 732247	5	221	36	05104620001051	AA97220-01 05104620001051 14 N/A Serum-1 11 / Day 1 1h
14	N/A	12 / Day 1 1 25h	757882 557	283605 092	2 672316	5	217	37	05104620001052	AA97220-01 05104620001052 14 N/A Serum-1 12 / Day 1 1 25h
14	N/A	13 / Day 1 1 5h	799429 202	290017 211	2 756489	5	223	38	05104620001053	AA97220-01 05104620001053 14 N/A Serum-1 13 / Day 1 1 5h
14	N/A	14 / Day 1 2h	842446 222	312860 335	2 692723	5	218	40	05104620001054	AA97220-01 05104620001054 14 N/A Serum-1 14 / Day 1 2h
14	N/A	14 / Day 1 2h	464237 47	192333 569	2 413710	5	196	41	05104620001070	AA97220-01 05104620001070 14 N/A Serum-1 14 / Day 1 2h
14	N/A	15 / Day 1 2 5h	808947 192	309375 524	2 614774	5	212	42	05104620001055	AA97220-01 05104620001055 14 N/A Serum-1 15 / Day 1 2 5h
14	N/A	16 / Day 1 3h	656754 335	258727 213	2 538405	5	206	43	05104620001056	AA97220-01 05104620001056 14 N/A Serum-1 16 / Day 1 3h
15	N/A	1 / Day 1 - 0 0333h	860133 148	268447 109	3 204107	5	260	46	05104620001169	AA97220-01 05104620001169 15 N/A Serum-1 1 / Day 1 - 0333h
15	N/A	1 / Day 1 - 0 0333h	665352 215	266095 028	2 500431	5	203	44	05104620001185	AA97220-01 05104620001185 15 N/A Serum-1 1 / Day 1 - 0333h
15	N/A	2 / Day 1 0h	873684 25	268547 948	3 253364	5	264	47	05104620001170	AA97220-01 05104620001170 15 N/A Serum-1 2 / Day 1 0h
15	N/A	3 / Day 1 0 05h	948192 482	296095 987	3 202315	5	260	48	05104620001171	AA97220-01 05104620001171 15 N/A Serum-1 3 / Day 1 05h
15	N/A	4 / Day 1 0 0833h	865594 287	270052 424	3 205282	5	260	49	05104620001172	AA97220-01 05104620001172 15 N/A Serum-1 4 / Day 1 0833h
15	N/A	5 / Day 1 0 125h	908170 128	282510 848	3 214638	5	261	50	05104620001173	AA97220-01 05104620001173 15 N/A Serum-1 5 / Day 1 125h
15	N/A	5 / Day 1 0 125h	683233 628	261255 957	2 615189	5	212	51	05104620001189	AA97220-01 05104620001189 15 N/A Serum-1 5 / Day 1 125h
15	N/A	6 / Day 1 0 1667h	879957 766	269360 822	3 266837	5	265	53	05104620001174	AA97220-01 05104620001174 15 N/A Serum-1 6 / Day 1 1667h
15	N/A	6 / Day 1 0 1667h	664950 123	267069 939	2 489798	5	202	54	05104620001190	AA97220-01 05104620001190 15 N/A Serum-1 6 / Day 1 1667h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
15	N/A	7 / Day 1 0 25h	940927 166	281216 08	3 345922	5	271	56	05104620001175	AA97220-01 05104620001175 15 N/A Serum-1 7 / Day 1 25h
15	N/A	7 / Day 1 0 25h	723747 803	282924 821	2 558092	5	207	55	05104620001191	AA97220-01 05104620001191 15 N/A Serum-1 7 / Day 1 25h
15	N/A	8 / Day 1 0 333h	717483 013	220415 337	3 255141	5	264	57	05104620001176	AA97220-01 05104620001176 15 N/A Serum-1 8 / Day 1 333h
15	N/A	8 / Day 1 0 333h	771321 095	299377 701	2 576415	5	209	58	05104620001192	AA97220-01 05104620001192 15 N/A Serum-1 8 / Day 1 333h
15	N/A	9 / Day 1 0 5h	946365 37	290794 251	3 254416	5	264	59	05104620001177	AA97220-01 05104620001177 15 N/A Serum-1 9 / Day 1 5h
15	N/A	9 / Day 1 0 5h	599815 688	229312 286	2 615715	5	212	61	05104620001193	AA97220-01 05104620001193 15 N/A Serum-1 9 / Day 1 5h
15	N/A	10 / Day 1 0 75h	947621 654	288375 971	3 286063	5	266	62	05104620001178	AA97220-01 05104620001178 15 N/A Serum-1 10 / Day 1 75h
15	N/A	10 / Day 1 0 75h	735537 748	277988 34	2 645930	5	214	63	05104620001194	AA97220-01 05104620001194 15 N/A Serum-1 10 / Day 1 75h
15	N/A	11 / Day 1 1h	1014667 856	308831 779	3 285503	5	266	64	05104620001179	AA97220-01 05104620001179 15 N/A Serum-1 11 / Day 1 1h
15	N/A	11 / Day 1 1h	671925 182	256691 326	2 617639	5	212	65	05104620001195	AA97220-01 05104620001195 15 N/A Serum-1 11 / Day 1 1h
15	N/A	12 / Day 1 1 25h	938913 103	299398 343	3 136000	5	254	66	05104620001180	AA97220-01 05104620001180 15 N/A Serum-1 12 / Day 1 1 25h
15	N/A	12 / Day 1 1 25h	693163 91	266157 667	2 604336	5	211	68	05104620001196	AA97220-01 05104620001196 15 N/A Serum-1 12 / Day 1 1 25h
15	N/A	13 / Day 1 1 5h	995669 488	316360 294	3 147264	5	255	69	05104620001181	AA97220-01 05104620001181 15 N/A Serum-1 13 / Day 1 1 5h
15	N/A	13 / Day 1 1 5h	765239 928	292756 884	2 613909	5	212	70	05104620001197	AA97220-01 05104620001197 15 N/A Serum-1 13 / Day 1 1 5h
15	N/A	14 / Day 1 2h	895702 747	287678 631	3 113553	5	252	72	05104620001182	AA97220-01 05104620001182 15 N/A Serum-1 14 / Day 1 2h
15	N/A	14 / Day 1 2h	799146 725	310055 132	2 577434	5	209	71	05104620001198	AA97220-01 05104620001198 15 N/A Serum-1 14 / Day 1 2h
15	N/A	15 / Day 1 2 5h	817990 333	275526 438	2 968827	5	241	74	05104620001183	AA97220-01 05104620001183 15 N/A Serum-1 15 / Day 1 2 5h
15	N/A	15 / Day 1 2 5h	738040 726	290040 351	2 544614	5	206	75	05104620001199	AA97220-01 05104620001199 15 N/A Serum-1 15 / Day 1 2 5h
15	N/A	16 / Day 1 3h	929293 885	312497 359	2 973766	5	241	77	05104620001184	AA97220-01 05104620001184 15 N/A Serum-1 16 / Day 1 3h
15	N/A	16 / Day 1 3h	843119 769	320329 733	2 632037	5	213	76	05104620001200	AA97220-01 05104620001200 15 N/A Serum-1 16 / Day 1 3h

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 33
Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		0	1606320 127	0 000000	-0 118		-0 118	0 0
9	0 00		0	1467765 4	0 000000	-0 118			
10	1 00	1 00000	13042 227	1579288 94	0 008258	0 987	-1 3		
11	2 00	0 250000	25530 964	1570976 7	0 016252	2 06	3 0		
12	4 00	0 0625000	52484 895	1668199 188	0 031462	4 09	2 3		
13	8 00	0 0156250	106079 755	1870225 079	0 056720	7 47	-6 6		
14	16 0	0 00390625	257898 909	2119802 785	0 121662	16 2	1 3		
15	40 0	0 000625000	534493 124	1779383 843	0 300381	40 1	0 3		
16	80 0	0 000156250	1169519 387	1946917 825	0 600703	80 3	0 4		
17	160	0 0000390625	2129175 914	1738638 015	1 224623	164	2 5		
18	200	0 0000250000	2506889 337	1698226 264	1 476181	197	-1 5		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:

Slope = 0 00747184661

Intercept = 0 000880990205

R-Squared = 0 9989

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 33
Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	2465540 573	1640775 745	1 502668	1	201		202		0 9
2	0 00	2263753 092	1484080 14	1 525358	1	204				
3	0 00	2340284 882	1547977 65	1 511834	1	202				
4	0 00	2366030 34	1570706 389	1 506348	1	201				
5	0 00	2292734 854	1540805 21	1 488011	1	199				
95	0 00	2678822 45	1759428 591	1 522553	1	204				
96	0 00	2811735 294	1866363 642	1 506531	1	202				
35	3 00	48359 915	2123672 442	0 022772	1	2 93	-2 3	2 80	-6 7	6 6
68	3 00	40463 964	1945261 709	0 020801	1	2 67	-11 0			
43	37 5	569425 594	2128270 496	0 267553	1	35 7	-4 8	35 8	-4 5	0 2
75	37 5	588897 078	2194119 606	0 268398	1	35 8	-4 5			
27	150	473427 625	2127422 563	0 222536	5	148	-1 3	146	-2 7	1 0
60	150	415360 813	1897809 262	0 218863	5	146	-2 7			
83	150	358507 453	1645837 888	0 217827	5	145	-3 3			
51	150	2167880 708	2032790 066	1 066456	1	143	-4 7	148	-1 3	4 3
93	150	1919006 131	1690831 569	1 134948	1	152	1 3			

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 33
Serum, Concentration of Cotinine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
14	N/A	5 / Day 1 0 125h	814570 158	2141533 335	0 380368	5	254	39	05104620001077	AA97220-01 05104620001077 14 N/A Serum-1 5 / Day 1 125h
14	N/A	5 / Day 1 0 125h	845579 427	2073827 359	0 407739	5	272	38	05104620001109	AA97220-01 05104620001109 14 N/A Serum-1 5 / Day 1 125h
14	N/A	6 / Day 1 0 1667h	807479 064	1938944 13	0 416453	5	278	40	05104620001078	AA97220-01 05104620001078 14 N/A Serum-1 6 / Day 1 1667h
14	N/A	6 / Day 1 0 1667h	697017 263	1919253 501	0 363171	5	242	42	05104620001094	AA97220-01 05104620001094 14 N/A Serum-1 6 / Day 1 1667h
14	N/A	6 / Day 1 0 1667h	793288 977	1965306 89	0 403646	5	270	41	05104620001110	AA97220-01 05104620001110 14 N/A Serum-1 6 / Day 1 1667h
14	N/A	7 / Day 1 0 25h	759236 452	1927871 351	0 393821	5	263	45	05104620001079	AA97220-01 05104620001079 14 N/A Serum-1 7 / Day 1 25h
14	N/A	7 / Day 1 0 25h	765769 433	2043466 869	0 374740	5	250	46	05104620001095	AA97220-01 05104620001095 14 N/A Serum-1 7 / Day 1 25h
14	N/A	7 / Day 1 0 25h	708624 234	1745540 802	0 405963	5	271	44	05104620001111	AA97220-01 05104620001111 14 N/A Serum-1 7 / Day 1 25h
14	N/A	8 / Day 1 0 333h	852522 331	2086683 05	0 408554	5	273	47	05104620001080	AA97220-01 05104620001080 14 N/A Serum-1 8 / Day 1 333h
14	N/A	8 / Day 1 0 333h	718302 573	1952884 432	0 367816	5	246	48	05104620001096	AA97220-01 05104620001096 14 N/A Serum-1 8 / Day 1 333h
14	N/A	8 / Day 1 0 333h	795522 558	1935317 398	0 411055	5	274	49	05104620001112	AA97220-01 05104620001112 14 N/A Serum-1 8 / Day 1 333h
14	N/A	9 / Day 1 0 5h	757115 455	1939339 991	0 390399	5	261	50	05104620001081	AA97220-01 05104620001081 14 N/A Serum-1 9 / Day 1 5h
14	N/A	9 / Day 1 0 5h	705248 518	1925756 735	0 366219	5	244	53	05104620001097	AA97220-01 05104620001097 14 N/A Serum-1 9 / Day 1 5h
14	N/A	9 / Day 1 0 5h	815955 447	2000962 495	0 407781	5	272	52	05104620001113	AA97220-01 05104620001113 14 N/A Serum-1 9 / Day 1 5h
14	N/A	10 / Day 1 0 75h	866518 987	2022124 033	0 428519	5	286	55	05104620001082	AA97220-01 05104620001082 14 N/A Serum-1 10 / Day 1 75h
14	N/A	10 / Day 1 0 75h	702065 107	1945555 341	0 360856	5	241	56	05104620001098	AA97220-01 05104620001098 14 N/A Serum-1 10 / Day 1 75h
14	N/A	10 / Day 1 0 75h	851368 56	2089203 925	0 407509	5	272	54	05104620001114	AA97220-01 05104620001114 14 N/A Serum-1 10 / Day 1 75h
14	N/A	11 / Day 1 1h	751208 421	1810590 416	0 414897	5	277	59	05104620001083	AA97220-01 05104620001083 14 N/A Serum-1 11 / Day 1 1h
14	N/A	11 / Day 1 1h	700035 84	1905446 704	0 367387	5	245	57	05104620001099	AA97220-01 05104620001099 14 N/A Serum-1 11 / Day 1 1h
14	N/A	11 / Day 1 1h	822369 072	2018608 726	0 407394	5	272	58	05104620001115	AA97220-01 05104620001115 14 N/A Serum-1 11 / Day 1 1h
14	N/A	12 / Day 1 1 25h	771984 411	1912924 389	0 403562	5	269	62	05104620001084	AA97220-01 05104620001084 14 N/A Serum-1 12 / Day 1 1 25h
14	N/A	12 / Day 1 1 25h	783946 698	1954565 785	0 401085	5	268	61	05104620001116	AA97220-01 05104620001116 14 N/A Serum-1 12 / Day 1 1 25h
14	N/A	13 / Day 1 1 5h	766809 856	1945022 586	0 394242	5	263	65	05104620001085	AA97220-01 05104620001085 14 N/A Serum-1 13 / Day 1 1 5h
14	N/A	13 / Day 1 1 5h	690112 897	1886668 968	0 365784	5	244	63	05104620001101	AA97220-01 05104620001101 14 N/A Serum-1 13 / Day 1 1 5h
14	N/A	13 / Day 1 1 5h	793122 762	1969975 68	0 402605	5	269	64	05104620001117	AA97220-01 05104620001117 14 N/A Serum-1 13 / Day 1 1 5h
14	N/A	14 / Day 1 2h	882134 615	2307892 864	0 382225	5	255	67	05104620001086	AA97220-01 05104620001086 14 N/A Serum-1 14 / Day 1 2h
14	N/A	14 / Day 1 2h	616030 131	1754379 497	0 351138	5	234	69	05104620001102	AA97220-01 05104620001102 14 N/A Serum-1 14 / Day 1 2h
14	N/A	14 / Day 1 2h	959695 463	2320037 364	0 413655	5	276	66	05104620001118	AA97220-01 05104620001118 14 N/A Serum-1 14 / Day 1 2h
14	N/A	15 / Day 1 2 5h	797419 315	2212722 783	0 360379	5	241	72	05104620001087	AA97220-01 05104620001087 14 N/A Serum-1 15 / Day 1 2 5h
14	N/A	15 / Day 1 2 5h	671936 112	2014797 123	0 333501	5	223	71	05104620001103	AA97220-01 05104620001103 14 N/A Serum-1 15 / Day 1 2 5h
14	N/A	15 / Day 1 2 5h	729869 975	1920701 727	0 380002	5	254	70	05104620001119	AA97220-01 05104620001119 14 N/A Serum-1 15 / Day 1 2 5h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
14	N/A	16 / Day 1 3h	686036 244	1928359 968	0 355762	5	237	76	05104620001088	AA97220-01 05104620001088 14 N/A Serum-1 16 / Day 1 3h
14	N/A	16 / Day 1 3h	578066 37	1785922 205	0 323679	5	216	73	05104620001104	AA97220-01 05104620001104 14 N/A Serum-1 16 / Day 1 3h
14	N/A	16 / Day 1 3h	823211 613	2189096 585	0 376051	5	251	74	05104620001120	AA97220-01 05104620001120 14 N/A Serum-1 16 / Day 1 3h
15	N/A	1 / Day 1 -0 0333h	574518 331	1919830 961	0 299255	5	200	77	05104620001137	AA97220-01 05104620001137 15 N/A Serum-1 1 / Day 1 - 0333h
15	N/A	4 / Day 1 0 0833h	639520 357	2059335 541	0 310547	5	207	78	05104620001124	AA97220-01 05104620001124 15 N/A Serum-1 4 / Day 1 0833h
15	N/A	7 / Day 1 0 25h	590154 494	1906437 104	0 309559	5	207	79	05104620001127	AA97220-01 05104620001127 15 N/A Serum-1 7 / Day 1 25h
15	N/A	8 / Day 1 0 333h	618393 092	1982262 712	0 311963	5	208	80	05104620001128	AA97220-01 05104620001128 15 N/A Serum-1 8 / Day 1 333h
15	N/A	10 / Day 1 0 75h	537338 362	1716499 676	0 313043	5	209	82	05104620001130	AA97220-01 05104620001130 15 N/A Serum-1 10 / Day 1 75h
15	N/A	10 / Day 1 0 75h	618847 653	2121609 836	0 291688	5	195	81	05104620001162	AA97220-01 05104620001162 15 N/A Serum-1 10 / Day 1 75h
15	N/A	11 / Day 1 1h	513257 157	1626025 987	0 315651	5	211	84	05104620001131	AA97220-01 05104620001131 15 N/A Serum-1 11 / Day 1 1h
15	N/A	11 / Day 1 1h	513247 195	1703416 545	0 301305	5	201	85	05104620001147	AA97220-01 05104620001147 15 N/A Serum-1 11 / Day 1 1h
15	N/A	12 / Day 1 1 25h	539196 618	1684940 141	0 320009	5	214	86	05104620001132	AA97220-01 05104620001132 15 N/A Serum-1 12 / Day 1 1 25h
15	N/A	14 / Day 1 2h	571761 158	1825985 131	0 313125	5	209	88	05104620001134	AA97220-01 05104620001134 15 N/A Serum-1 13 / Day 1 2h
15	N/A	14 / Day 1 2h	509425 177	1865137 298	0 273130	5	182	87	05104620001166	AA97220-01 05104620001166 15 N/A Serum-1 14 / Day 1 2h
16	N/A	2 / Day 1 0h	2594352 944	2002262 322	*1 295711	1	*173	89	05104620001266	AA97220-01 05104620001266 16 N/A Serum-1 2 / Day 1 0h
16	N/A	3 / Day 1 0 05h	444324 849	1678553 931	0 264707	5	177	90	05104620001267	AA97220-01 05104620001267 16 N/A Serum-1 3 / Day 1 05h
16	N/A	9 / Day 1 0 5h	440355 61	1641585 909	0 268250	5	179	91	05104620001273	AA97220-01 05104620001273 16 N/A Serum-1 9 / Day 1 5h
16	N/A	13 / Day 1 1 5h	435432 698	1628706 582	0 267349	5	178	92	05104620001277	AA97220-01 05104620001277 16 N/A Serum-1 13 / Day 1 1 5h
17	N/A	1 / Day 1 -0 0333h	3964734 567	2188604 927	*1 811535	1	*AAR>(200)	20	05104620001281	AA97220-01 05104620001281 17 N/A Serum-1 1 / Day 1 - 0333h
17	N/A	2 / Day 1 0h	3146559 549	1696485 237	*1 854752	1	*AAR>(200)	21	05104620001282	AA97220-01 05104620001282 17 N/A Serum-1 2 / Day 1 0h
17	N/A	3 / Day 1 0 05h	3689599 738	2102035 947	*1 755251	1	*AAR>(200)	22	05104620001283	AA97220-01 05104620001283 17 N/A Serum-1 3 / Day 1 05h
17	N/A	4 / Day 1 0 0833h	3837481 002	2134026 133	*1 798235	1	*AAR>(200)	23	05104620001284	AA97220-01 05104620001284 17 N/A Serum-1 4 / Day 1 0833h
17	N/A	5 / Day 1 0 125h	3137307 172	1755315 576	*1 787318	1	*AAR>(200)	24	05104620001285	AA97220-01 05104620001285 17 N/A Serum-1 5 / Day 1 125h
17	N/A	6 / Day 1 0 1667h	3785931 089	2108780 405	*1 795318	1	*AAR>(200)	25	05104620001286	AA97220-01 05104620001286 17 N/A Serum-1 6 / Day 1 1667h
17	N/A	7 / Day 1 0 25h	3061146 746	1758945 177	*1 740331	1	*AAR>(200)	26	05104620001287	AA97220-01 05104620001287 17 N/A Serum-1 7 / Day 1 25h
17	N/A	8 / Day 1 0 333h	3729803 447	2068505 788	*1 803139	1	*AAR>(200)	28	05104620001288	AA97220-01 05104620001288 17 N/A Serum-1 8 / Day 1 333h
17	N/A	9 / Day 1 0 5h	3116531 698	1711217 548	*1 821236	1	*AAR>(200)	29	05104620001289	AA97220-01 05104620001289 17 N/A Serum-1 9 / Day 1 5h
17	N/A	10 / Day 1 0 75h	2853220 877	1635621 224	*1 744426	1	*AAR>(200)	30	05104620001290	AA97220-01 05104620001290 17 N/A Serum-1 10 / Day 1 75h
17	N/A	11 / Day 1 1h	2931270 303	1614210 564	*1 815916	1	*AAR>(200)	31	05104620001291	AA97220-01 05104620001291 17 N/A Serum-1 11 / Day 1 1h
17	N/A	12 / Day 1 1 25h	2989020 448	1735578 076	*1 722205	1	*AAR>(200)	32	05104620001292	AA97220-01 05104620001292 17 N/A Serum-1 12 / Day 1 1 25h
17	N/A	13 / Day 1 1 5h	3652375 024	2110514 842	*1 730561	1	*AAR>(200)	33	05104620001293	AA97220-01 05104620001293 17 N/A Serum-1 13 / Day 1 1 5h
17	N/A	14 / Day 1 2h	2969543 699	1733017 71	*1 713510	1	*AAR>(200)	34	05104620001294	AA97220-01 05104620001294 17 N/A Serum-1 14 / Day 1 2h
17	N/A	15 / Day 1 2 5h	3487676 376	2008812 323	*1 736188	1	*AAR>(200)	36	05104620001295	AA97220-01 05104620001295 17 N/A Serum-1 15 / Day 1 2 5h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
17	N/A	16 / Day 1 3h	2931637 671	1739131 098	*1 685691	1	*AAR>(200)	37	05104620001296	AA97220-01 05104620001296 17 N/A Serum-1 16 / Day 1 3h

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

* - Sample Rejected

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 36
Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		0	285013 232	0 000000	-0 101		-0 101	0 0
9	0 00		0	299396 229	0 000000	-0 101			
10	1 00	1 00000	19606 782	292558 822	0 067018	0 986	-1 4		
11	2 00	0 250000	42486 457	327699 383	0 129651	2 00	0 0		
12	4 00	0 0625000	76854 405	287347 27	0 267462	4 24	6 0		
13	8 00	0 0156250	152371 257	305257 645	0 499156	7 99	-0 1		
14	16 0	0 00390625	268001 43	269328 705	0 995072	16 0	0 0		
15	40 0	0 000625000	704771 707	291102 095	2 421046	39 2	-2 0		
16	80 0	0 000156250	1384023 661	281086 089	4 923843	79 7	-0 4		
17	160	0 0000390625	2790686 269	282151 606	9 890733	160	0 0		
18	200	0 0000250000	3167050 274	262917 769	12 045783	195	-2 5		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:
Slope = 0 0616700072
Intercept = 0 00623567958
R-Squared = 0 9992

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)
AAR - Concentration Found is Greater than 200 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 36
Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	3315831 407	270192 244	12 272119	1	199		198		1 3
2	0 00	3400807 151	274579 335	12 385517	1	201				
3	0 00	3548113 793	289762 625	12 244898	1	198				
4	0 00	3471669 804	279084 101	12 439511	1	202				
5	0 00	3279356 921	269958 545	12 147631	1	197				
90	0 00	2397067 09	200438 952	11 959088	1	194				
91	0 00	2599530 903	212674 204	12 223066	1	198				
35	3 00	75581 779	392383 035	0 192622	1	3 02	0 7	3 00	0 0	1 2
67	3 00	39895 962	210668 298	0 189378	1	2 97	-1 0			
43	37 5	752549 215	327502 844	2 297840	1	37 2	-0 8	36 7	-2 1	1 9
75	37 5	423777 182	189490 189	2 236407	1	36 2	-3 5			
27	150	690330 8	385315 22	1 791600	5	145	-3 3	144	-4 0	0 8
59	150	366606 572	207051 196	1 770608	5	143	-4 7			
83	150	295413 109	165059 358	1 789739	5	145	-3 3			
51	150	2067407 167	237808 861	8 693567	1	141	-6 0	140	-6 7	1 0
88	150	1613899 329	188340 348	8 569058	1	139	-7 3			

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 36
Serum, Concentration of Cotinine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
10	N/A	11 / Day 1 1h	1146571 17	298350 05	3 843040	5	311	20	05104620000731	AA97220-01 05104620000731 10 N/A Serum-1 11 / Day 1 1h
10	N/A	11 / Day 1 1h	1082093 342	335578 21	3 224564	5	261	21	05104620000747	AA97220-01 05104620000747 10 N/A Serum-1 11 / Day 1 1h
10	N/A	12 / Day 1 1 25h	1261882 178	327187 041	3 856761	5	312	22	05104620000732	AA97220-01 05104620000732 10 N/A Serum-1 12 / Day 1 1 25h
10	N/A	12 / Day 1 1 25h	1095196 031	343212 566	3 191014	5	258	23	05104620000748	AA97220-01 05104620000748 10 N/A Serum-1 12 / Day 1 1 25h
10	N/A	13 / Day 1 1 5h	1521866 555	401067 644	3 794538	5	307	25	05104620000733	AA97220-01 05104620000733 10 N/A Serum-1 13 / Day 1 1 5h
10	N/A	13 / Day 1 1 5h	1178062 023	371414 505	3 171826	5	257	24	05104620000749	AA97220-01 05104620000749 10 N/A Serum-1 13 / Day 1 1 5h
10	N/A	14 / Day 1 2h	1235937 972	374068 512	3 304042	5	267	28	05104620000734	AA97220-01 05104620000734 10 N/A Serum-1 14 / Day 1 2h
10	N/A	14 / Day 1 2h	1271233 645	403307 929	3 152017	5	255	26	05104620000750	AA97220-01 05104620000750 10 N/A Serum-1 14 / Day 1 2h
10	N/A	15 / Day 1 2 5h	1553168 303	421358 953	3 686093	5	298	30	05104620000735	AA97220-01 05104620000735 10 N/A Serum-1 15 / Day 1 2 5h
10	N/A	15 / Day 1 2 5h	1283619 923	415760 618	3 087401	5	250	29	05104620000751	AA97220-01 05104620000751 10 N/A Serum-1 15 / Day 1 2 5h
10	N/A	16 / Day 1 3h	1368147 154	397813 65	3 439166	5	278	31	05104620000736	AA97220-01 05104620000736 10 N/A Serum-1 16 / Day 1 3h
10	N/A	16 / Day 1 3h	1378361 399	447886 906	3 077476	5	249	32	05104620000752	AA97220-01 05104620000752 10 N/A Serum-1 16 / Day 1 3h
11	N/A	1 / Day 1 - 0 0333h	656370 376	236868 936	2 771028	5	224	52	05104620000817	AA97220-01 05104620000817 11 N/A Serum-1 1 / Day 1 - 0333h
11	N/A	1 / Day 1 - 0 0333h	1119777 48	358560 473	3 122981	5	253	33	05104620000865	AA97220-01 05104620000865 11 N/A Serum-1 1 / Day 1 - 0333h
11	N/A	2 / Day 1 0h	659551 94	235945 693	2 795355	5	226	53	05104620000818	AA97220-01 05104620000818 11 N/A Serum-1 2 / Day 1 0h
11	N/A	2 / Day 1 0h	1207556 634	392932 954	3 073187	5	249	34	05104620000866	AA97220-01 05104620000866 11 N/A Serum-1 2 / Day 1 0h
11	N/A	3 / Day 1 0 05h	613528 225	221192 923	2 773724	5	224	54	05104620000819	AA97220-01 05104620000819 11 N/A Serum-1 3 / Day 1 0 05h
11	N/A	3 / Day 1 0 05h	1105954 194	352798 833	3 134801	5	254	36	05104620000867	AA97220-01 05104620000867 11 N/A Serum-1 3 / Day 1 0 05h
11	N/A	4 / Day 1 0 0833h	544818 625	196141 845	2 777677	5	225	55	05104620000820	AA97220-01 05104620000820 11 N/A Serum-1 4 / Day 1 0 0833h
11	N/A	4 / Day 1 0 0833h	1102564 137	370659 388	2 974602	5	241	37	05104620000868	AA97220-01 05104620000868 11 N/A Serum-1 4 / Day 1 0 0833h
11	N/A	5 / Day 1 0 125h	580455 292	209220 539	2 774371	5	224	56	05104620000821	AA97220-01 05104620000821 11 N/A Serum-1 5 / Day 1 0 125h
11	N/A	5 / Day 1 0 125h	1070245 229	340699 791	3 141315	5	254	38	05104620000869	AA97220-01 05104620000869 11 N/A Serum-1 5 / Day 1 0 125h
11	N/A	6 / Day 1 0 1667h	584487 097	206704 945	2 827640	5	229	57	05104620000822	AA97220-01 05104620000822 11 N/A Serum-1 6 / Day 1 0 1667h
11	N/A	6 / Day 1 0 1667h	1000746 147	322777 15	3 100424	5	251	39	05104620000870	AA97220-01 05104620000870 11 N/A Serum-1 6 / Day 1 0 1667h
11	N/A	7 / Day 1 0 25h	567944 895	200551 913	2 831910	5	229	58	05104620000823	AA97220-01 05104620000823 11 N/A Serum-1 7 / Day 1 0 25h
11	N/A	7 / Day 1 0 25h	1018980 63	327070 544	3 115477	5	252	40	05104620000871	AA97220-01 05104620000871 11 N/A Serum-1 7 / Day 1 0 25h
11	N/A	8 / Day 1 0 333h	565807 225	202811 592	2 789817	5	226	60	05104620000824	AA97220-01 05104620000824 11 N/A Serum-1 8 / Day 1 0 333h
11	N/A	8 / Day 1 0 333h	1054279 359	329083 179	3 203687	5	259	41	05104620000872	AA97220-01 05104620000872 11 N/A Serum-1 8 / Day 1 0 333h
11	N/A	9 / Day 1 0 5h	585836 139	212270 455	2 759857	5	223	61	05104620000825	AA97220-01 05104620000825 11 N/A Serum-1 9 / Day 1 0 5h
11	N/A	9 / Day 1 0 5h	1068764 403	331073 702	3 228177	5	261	42	05104620000873	AA97220-01 05104620000873 11 N/A Serum-1 9 / Day 1 0 5h
11	N/A	10 / Day 1 0 75h	560254 25	197075 126	2 842846	5	230	62	05104620000826	AA97220-01 05104620000826 11 N/A Serum-1 10 / Day 1 0 75h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
11	N/A	10 / Day 1 0 75h	1008960 885	322424 119	3 129297	5	253	44	05104620000874	AA97220-01 05104620000874 11 N/A Serum-1 10 / Day 1 75h
11	N/A	11 / Day 1 1h	603473 572	208810 487	2 890054	5	234	63	05104620000827	AA97220-01 05104620000827 11 N/A Serum-1 11 / Day 1 1h
11	N/A	11 / Day 1 1h	922085 182	297044 457	3 104199	5	251	45	05104620000875	AA97220-01 05104620000875 11 N/A Serum-1 11 / Day 1 1h
11	N/A	12 / Day 1 1 25h	588280 412	207829 663	2 830589	5	229	64	05104620000828	AA97220-01 05104620000828 11 N/A Serum-1 12 / Day 1 1 25h
11	N/A	12 / Day 1 1 25h	943540 875	299353 528	3 151928	5	255	46	05104620000876	AA97220-01 05104620000876 11 N/A Serum-1 12 / Day 1 1 25h
11	N/A	13 / Day 1 1 5h	631233 932	225884 942	2 794493	5	226	65	05104620000829	AA97220-01 05104620000829 11 N/A Serum-1 13 / Day 1 1 5h
11	N/A	13 / Day 1 1 5h	810573 308	268023 95	3 024257	5	245	47	05104620000877	AA97220-01 05104620000877 11 N/A Serum-1 13 / Day 1 1 5h
11	N/A	14 / Day 1 2h	580364 947	205801 934	2 820017	5	228	66	05104620000830	AA97220-01 05104620000830 11 N/A Serum-1 14 / Day 1 2h
11	N/A	14 / Day 1 2h	834368 478	274497 067	3 039626	5	246	48	05104620000878	AA97220-01 05104620000878 11 N/A Serum-1 14 / Day 1 2h
11	N/A	15 / Day 1 2 5h	507105 317	186395 349	2 720590	5	220	68	05104620000831	AA97220-01 05104620000831 11 N/A Serum-1 15 / Day 1 2 5h
11	N/A	15 / Day 1 2 5h	820674 453	276568 776	2 967343	5	240	49	05104620000879	AA97220-01 05104620000879 11 N/A Serum-1 15 / Day 1 2 5h
11	N/A	16 / Day 1 3h	509327 525	181614 702	2 804440	5	227	69	05104620000832	AA97220-01 05104620000832 11 N/A Serum-1 16 / Day 1 3h
11	N/A	16 / Day 1 3h	678462 782	236497 84	2 868791	5	232	50	05104620000880	AA97220-01 05104620000880 11 N/A Serum-1 16 / Day 1 3h
12	N/A	1 / Day 1 - 0 0333h	1101167 713	168546 667	6 533311	5	529	70	05104620000945	AA97220-01 05104620000945 12 N/A Serum-1 1 / Day 1 - 0333h
12	N/A	2 / Day 1 0h	1183435 488	175129 54	6 757486	5	547	71	05104620000946	AA97220-01 05104620000946 12 N/A Serum-1 2 / Day 1 0h
12	N/A	3 / Day 1 0 05h	1108511 453	165446 515	6 700120	5	543	72	05104620000947	AA97220-01 05104620000947 12 N/A Serum-1 3 / Day 1 0 05h
12	N/A	4 / Day 1 0 0833h	1180494 332	179026 757	6 593955	5	534	73	05104620000948	AA97220-01 05104620000948 12 N/A Serum-1 4 / Day 1 0 0833h
12	N/A	5 / Day 1 0 125h	1240130 598	185542 81	6 683798	5	541	74	05104620000949	AA97220-01 05104620000949 12 N/A Serum-1 5 / Day 1 0 125h
12	N/A	6 / Day 1 0 1667h	1207904 79	181582 5	6 652099	5	539	76	05104620000950	AA97220-01 05104620000950 12 N/A Serum-1 6 / Day 1 0 1667h
12	N/A	7 / Day 1 0 25h	1261671 257	192118 956	6 567136	5	532	77	05104620000951	AA97220-01 05104620000951 12 N/A Serum-1 7 / Day 1 0 25h
12	N/A	8 / Day 1 0 333h	1333601 365	192620 604	6 923462	5	561	78	05104620000952	AA97220-01 05104620000952 12 N/A Serum-1 8 / Day 1 0 333h
12	N/A	9 / Day 1 0 5h	1227383 143	180386 987	6 804167	5	551	79	05104620000953	AA97220-01 05104620000953 12 N/A Serum-1 9 / Day 1 0 5h
12	N/A	10 / Day 1 0 75h	1026608 556	152507 68	6 731520	5	545	80	05104620000954	AA97220-01 05104620000954 12 N/A Serum-1 10 / Day 1 0 75h
12	N/A	11 / Day 1 1h	1084520 415	165182 962	6 565571	5	532	81	05104620000955	AA97220-01 05104620000955 12 N/A Serum-1 11 / Day 1 1h
12	N/A	12 / Day 1 1 25h	1056437 275	163859 283	6 447223	5	522	82	05104620000956	AA97220-01 05104620000956 12 N/A Serum-1 12 / Day 1 1 25h
12	N/A	13 / Day 1 1 5h	1013207 847	157075 892	6 450435	5	522	84	05104620000957	AA97220-01 05104620000957 12 N/A Serum-1 13 / Day 1 1 5h
12	N/A	14 / Day 1 2h	1085049 973	171943 967	6 310486	5	511	85	05104620000958	AA97220-01 05104620000958 12 N/A Serum-1 14 / Day 1 2h
12	N/A	15 / Day 1 2 5h	1093994 843	170615 653	6 412043	5	519	86	05104620000959	AA97220-01 05104620000959 12 N/A Serum-1 15 / Day 1 2 5h
12	N/A	16 / Day 1 3h	886883 355	137619 943	6 444439	5	522	87	05104620000960	AA97220-01 05104620000960 12 N/A Serum-1 16 / Day 1 3h

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 37
Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		0	1444197 554	0 000000	0 0536		0 0536	0 0
9	0 00		0	1537374 727	0 000000	0 0536			
10	1 00	1 00000	11109 015	1556228 308	0 007138	1 00	0 0		
11	2 00	0 250000	21216 712	1472973 567	0 014404	1 97	-1 5		
12	4 00	0 0625000	48616 532	1561908 802	0 031126	4 19	4 8		
13	8 00	0 0156250	86913	1512969 124	0 057445	7 68	-4 0		
14	16 0	0 00390625	173248 298	1440960 628	0 120231	16 0	0 0		
15	40 0	0 000625000	482312 523	1604923 459	0 300521	40 0	0 0		
16	80 0	0 000156250	986310 266	1627623 031	0 605982	80 5	0 6		
17	160	0 0000390625	2223510 138	1822554 94	1 219996	162	1 3		
18	200	0 0000250000	2559423 334	1719522 178	1 488450	198	-1 0		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:
Slope = 0 00753042022
Intercept = -0 000403873893
R-Squared = 0 9993

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)
AAR - Concentration Found is Greater than 200 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 37
Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	2375668 554	1596258 238	1 488273	1	198		200		1 7
2	0 00	2444388 885	1624989 729	1 504249	1	200				
3	0 00	2651760 97	1796177 664	1 476336	1	196				
4	0 00	2448768 134	1608731 428	1 522173	1	202				
5	0 00	2372901 43	1576255 486	1 505404	1	200				
93	0 00	2323247 056	1540042 603	1 508560	1	200				
94	0 00	2604095 663	1670992 624	1 558412	1	207				
35	3 00	35913 205	1625100 795	0 022099	1	2 99	-0 3	3 05	1 7	2 6
67	3 00	36215 488	1576909 341	0 022966	1	3 10	3 3			
43	37 5	425628 979	1570194 436	0 271068	1	36 1	-3 7	37 1	-1 1	3 8
75	37 5	491562 96	1717850 864	0 286150	1	38 1	1 6			
27	150	360820 498	1667871 909	0 216336	5	144	-4 0	144	-4 0	0 7
59	150	321371 752	1500050 121	0 214241	5	143	-4 7			
83	150	302973 668	1393831 281	0 217368	5	145	-3 3			
51	150	1779332 839	1652460 202	1 076778	1	143	-4 7	146	-2 7	2 4
91	150	1515771 757	1362135 733	1 112791	1	148	-1 3			

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 37
Serum, Concentration of Cotinine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
03	N/A	1 / Day 1 - 0 0333h	572200 557	1500257 233	0 381402	5	254	20	05104620000161	AA97220-01 05104620000161 03 N/A Serum-1 1 / Day 1 - 0333h
03	N/A	1 / Day 1 - 0 0333h	610211 336	1619880 43	0 376701	5	250	21	05104620000177	AA97220-01 05104620000177 03 N/A Serum-1 1 / Day 1 - 0333h
03	N/A	1 / Day 1 - 0 0333h	634808 089	1804605 58	0 351771	5	234	22	05104620000193	AA97220-01 05104620000193 03 N/A Serum-1 1 / Day 1 - 0333h
03	N/A	2 / Day 1 0h	665229 62	1722770 722	0 386139	5	257	23	05104620000162	AA97220-01 05104620000162 03 N/A Serum-1 2 / Day 1 0h
03	N/A	2 / Day 1 0h	608610 852	1646511 755	0 369637	5	246	24	05104620000178	AA97220-01 05104620000178 03 N/A Serum-1 2 / Day 1 0h
03	N/A	2 / Day 1 0h	604304 546	1679272 155	0 359861	5	239	25	05104620000194	AA97220-01 05104620000194 03 N/A Serum-1 2 / Day 1 0h
03	N/A	3 / Day 1 0 05h	632316 849	1667010 844	0 379312	5	252	26	05104620000163	AA97220-01 05104620000163 03 N/A Serum-1 3 / Day 1 05h
03	N/A	3 / Day 1 0 05h	595453 692	1600817 281	0 371969	5	247	29	05104620000179	AA97220-01 05104620000179 03 N/A Serum-1 3 / Day 1 05h
03	N/A	3 / Day 1 0 05h	582235 26	1552384 889	0 375059	5	249	28	05104620000195	AA97220-01 05104620000195 03 N/A Serum-1 3 / Day 1 05h
03	N/A	4 / Day 1 0 0833h	635314 195	1606738 278	0 395406	5	263	32	05104620000164	AA97220-01 05104620000164 03 N/A Serum-1 4 / Day 1 0833h
03	N/A	4 / Day 1 0 0833h	633611 048	1708057 653	0 370954	5	247	31	05104620000180	AA97220-01 05104620000180 03 N/A Serum-1 4 / Day 1 0833h
03	N/A	4 / Day 1 0 0833h	585309 742	1611344 053	0 363243	5	241	30	05104620000196	AA97220-01 05104620000196 03 N/A Serum-1 4 / Day 1 0833h
03	N/A	5 / Day 1 0 125h	675923 507	1741136 098	0 388208	5	258	36	05104620000165	AA97220-01 05104620000165 03 N/A Serum-1 5 / Day 1 125h
03	N/A	5 / Day 1 0 125h	568887 501	1601883 512	0 355137	5	236	34	05104620000181	AA97220-01 05104620000181 03 N/A Serum-1 5 / Day 1 125h
03	N/A	5 / Day 1 0 125h	576597 665	1633372 151	0 353011	5	235	33	05104620000197	AA97220-01 05104620000197 03 N/A Serum-1 5 / Day 1 125h
03	N/A	6 / Day 1 0 1667h	690582 835	1812959 101	0 380915	5	253	37	05104620000166	AA97220-01 05104620000166 03 N/A Serum-1 6 / Day 1 1667h
03	N/A	6 / Day 1 0 1667h	667537 449	1854121 235	0 360029	5	239	39	05104620000182	AA97220-01 05104620000182 03 N/A Serum-1 6 / Day 1 1667h
03	N/A	6 / Day 1 0 1667h	604810 629	1737619 627	0 348068	5	231	38	05104620000198	AA97220-01 05104620000198 03 N/A Serum-1 6 / Day 1 1667h
03	N/A	7 / Day 1 0 25h	610232 474	1724205 292	0 353921	5	235	40	05104620000167	AA97220-01 05104620000167 03 N/A Serum-1 7 / Day 1 25h
03	N/A	7 / Day 1 0 25h	585655 181	1670912 339	0 350500	5	233	41	05104620000183	AA97220-01 05104620000183 03 N/A Serum-1 7 / Day 1 25h
03	N/A	7 / Day 1 0 25h	579198 089	1661408 837	0 348619	5	232	42	05104620000199	AA97220-01 05104620000199 03 N/A Serum-1 7 / Day 1 25h
03	N/A	8 / Day 1 0 333h	587530 677	1559210 847	0 376813	5	250	45	05104620000168	AA97220-01 05104620000168 03 N/A Serum-1 8 / Day 1 333h
03	N/A	8 / Day 1 0 333h	588084 743	1661243 739	0 354003	5	235	44	05104620000184	AA97220-01 05104620000184 03 N/A Serum-1 8 / Day 1 333h
03	N/A	8 / Day 1 0 333h	676276 068	1857163 602	0 364145	5	242	46	05104620000200	AA97220-01 05104620000200 03 N/A Serum-1 8 / Day 1 333h
03	N/A	9 / Day 1 0 5h	702587 409	1927068 077	0 364589	5	242	49	05104620000169	AA97220-01 05104620000169 03 N/A Serum-1 9 / Day 1 5h
03	N/A	9 / Day 1 0 5h	610566 623	1713740 057	0 356277	5	237	48	05104620000185	AA97220-01 05104620000185 03 N/A Serum-1 9 / Day 1 5h
03	N/A	9 / Day 1 0 5h	653975 438	1848514 016	0 353784	5	235	47	05104620000201	AA97220-01 05104620000201 03 N/A Serum-1 9 / Day 1 5h
03	N/A	10 / Day 1 0 75h	695244 213	1854722 664	0 374851	5	249	52	05104620000170	AA97220-01 05104620000170 03 N/A Serum-1 10 / Day 1 75h
03	N/A	10 / Day 1 0 75h	605117 553	1593766 351	0 379678	5	252	53	05104620000186	AA97220-01 05104620000186 03 N/A Serum-1 10 / Day 1 75h
03	N/A	10 / Day 1 0 75h	621280 746	1719918 047	0 361227	5	240	50	05104620000202	AA97220-01 05104620000202 03 N/A Serum-1 10 / Day 1 75h
03	N/A	11 / Day 1 1h	624412 145	1638745 309	0 381031	5	253	55	05104620000171	AA97220-01 05104620000171 03 N/A Serum-1 11 / Day 1 1h
03	N/A	11 / Day 1 1h	579966 93	1630274 742	0 355748	5	236	56	05104620000187	AA97220-01 05104620000187 03 N/A Serum-1 11 / Day 1 1h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
03	N/A	11 / Day 1 1h	638450 608	1813582 148	0 352038	5	234	54	05104620000203	AA97220-01 05104620000203 03 N/A Serum-1 11 / Day 1 1h
03	N/A	12 / Day 1 1 25h	561464 462	1518000 422	0 369871	5	246	58	05104620000172	AA97220-01 05104620000172 03 N/A Serum-1 12 / Day 1 1 25h
03	N/A	12 / Day 1 1 25h	514045 878	1429575 372	0 359579	5	239	60	05104620000188	AA97220-01 05104620000188 03 N/A Serum-1 12 / Day 1 1 25h
03	N/A	12 / Day 1 1 25h	560527 177	1542141 199	0 363473	5	242	57	05104620000204	AA97220-01 05104620000204 03 N/A Serum-1 12 / Day 1 1 25h
03	N/A	13 / Day 1 1 5h	523473 942	1369417 865	0 382260	5	254	63	05104620000173	AA97220-01 05104620000173 03 N/A Serum-1 13 / Day 1 1 5h
03	N/A	13 / Day 1 1 5h	450324 763	1332901 121	0 337853	5	225	61	05104620000189	AA97220-01 05104620000189 03 N/A Serum-1 13 / Day 1 1 5h
03	N/A	13 / Day 1 1 5h	504856 668	1426341 572	0 353952	5	235	62	05104620000205	AA97220-01 05104620000205 03 N/A Serum-1 13 / Day 1 1 5h
03	N/A	14 / Day 1 2h	519945 587	1450308 485	0 358507	5	238	64	05104620000174	AA97220-01 05104620000174 03 N/A Serum-1 14 / Day 1 2h
03	N/A	14 / Day 1 2h	553451 102	1553319 429	0 356302	5	237	66	05104620000190	AA97220-01 05104620000190 03 N/A Serum-1 14 / Day 1 2h
03	N/A	14 / Day 1 2h	553338 953	1528006 938	0 362131	5	241	65	05104620000206	AA97220-01 05104620000206 03 N/A Serum-1 14 / Day 1 2h
03	N/A	15 / Day 1 2 5h	597507 599	1627354 591	0 367165	5	244	68	05104620000175	AA97220-01 05104620000175 03 N/A Serum-1 15 / Day 1 2 5h
03	N/A	15 / Day 1 2 5h	549833 578	1548961 083	0 354969	5	236	69	05104620000191	AA97220-01 05104620000191 03 N/A Serum-1 15 / Day 1 2 5h
03	N/A	15 / Day 1 2 5h	594740 898	1711527 509	0 347491	5	231	70	05104620000207	AA97220-01 05104620000207 03 N/A Serum-1 15 / Day 1 2 5h
03	N/A	16 / Day 1 3h	536353 058	1439494 648	0 372598	5	248	71	05104620000176	AA97220-01 05104620000176 03 N/A Serum-1 16 / Day 1 3h
03	N/A	16 / Day 1 3h	524269 363	1479643 564	0 354321	5	236	73	05104620000192	AA97220-01 05104620000192 03 N/A Serum-1 16 / Day 1 3h
03	N/A	16 / Day 1 3h	491145 172	1427297 445	0 344108	5	229	72	05104620000208	AA97220-01 05104620000208 03 N/A Serum-1 16 / Day 1 3h
04	N/A	10 / Day 1 0 75h	283586 144	1363698 283	0 207954	5	138	74	05104620000314	AA97220-01 05104620000314 04 N/A Serum-1 10 / Day 1 75h
13	N/A	11 / Day 1 1h	1875807 846	1406431 1	1 333736	1	177	76	05104620000971	AA97220-01 05104620000971 13 N/A Serum-1 11 / Day 1 1h
14	N/A	1 / Day 1 - 0 0333h	660403 523	1552512 276	0 425377	5	283	78	05104620001073	AA97220-01 05104620001073 14 N/A Serum-1 1 / Day 1 - 0333h
14	N/A	1 / Day 1 - 0 0333h	591359 517	1555214 184	0 380243	5	253	79	05104620001089	AA97220-01 05104620001089 14 N/A Serum-1 1 / Day 1 - 0333h
14	N/A	1 / Day 1 - 0 0333h	600646 587	1507736 942	0 398376	5	265	77	05104620001105	AA97220-01 05104620001105 14 N/A Serum-1 1 / Day 1 - 0333h
14	N/A	2 / Day 1 0h	581607 05	1381777 983	0 420912	5	280	82	05104620001074	AA97220-01 05104620001074 14 N/A Serum-1 2 / Day 1 0h
14	N/A	2 / Day 1 0h	553719 418	1449120 661	0 382107	5	254	80	05104620001090	AA97220-01 05104620001090 14 N/A Serum-1 2 / Day 1 0h
14	N/A	2 / Day 1 0h	505282 436	1360490 442	0 371397	5	247	81	05104620001106	AA97220-01 05104620001106 14 N/A Serum-1 2 / Day 1 0h
14	N/A	3 / Day 1 0 05h	600550 405	1458356 167	0 411800	5	274	86	05104620001075	AA97220-01 05104620001075 14 N/A Serum-1 3 / Day 1 05h
14	N/A	3 / Day 1 0 05h	553631 362	1510281 247	0 366575	5	244	84	05104620001091	AA97220-01 05104620001091 14 N/A Serum-1 3 / Day 1 05h
14	N/A	3 / Day 1 0 05h	582549 266	1547073 986	0 376549	5	250	85	05104620001107	AA97220-01 05104620001107 14 N/A Serum-1 3 / Day 1 05h
14	N/A	4 / Day 1 0 0833h	649648 742	1540431 496	0 421732	5	280	88	05104620001076	AA97220-01 05104620001076 14 N/A Serum-1 4 / Day 1 0833h
14	N/A	4 / Day 1 0 0833h	571935 074	1562303 71	0 366084	5	243	89	05104620001092	AA97220-01 05104620001092 14 N/A Serum-1 4 / Day 1 0833h
14	N/A	4 / Day 1 0 0833h	555664 361	1469268 194	0 378191	5	251	87	05104620001108	AA97220-01 05104620001108 14 N/A Serum-1 4 / Day 1 0833h
14	N/A	5 / Day 1 0 125h	520925 215	1413847 876	0 368445	5	245	90	05104620001093	AA97220-01 05104620001093 14 N/A Serum-1 5 / Day 1 125h

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 38
Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		0	2106939 148	0 000000	-0 0873		-0 0873	0 0
9	0 00		0	2402630 251	0 000000	-0 0873			
10	1 00	1 00000	15477 122	1925076 397	0 008040	1 03	3 0		
11	2 00	0 250000	28096 4	1958122 715	0 014349	1 90	-5 0		
12	4 00	0 0625000	61113 586	2057716 809	0 029700	4 02	0 5		
13	8 00	0 0156250	128273 952	2187839 819	0 058630	8 03	0 4		
14	16 0	0 00390625	243761 507	2201521 525	0 110724	15 2	-5 0		
15	40 0	0 000625000	607119 99	2108783 104	0 287901	39 8	-0 5		
16	80 0	0 000156250	1198548 265	2055994 293	0 582953	80 6	0 8		
17	160	0 0000390625	2555533 548	2184251 673	1 169981	162	1 3		
18	200	0 0000250000	2865873 502	1892589 302	1 514261	210	5 0		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:

Slope = 0 00722264304

Intercept = 0 000630754643

R-Squared = 0 9987

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 38
Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	2952508 401	2029890 24	1 454516	1	201		202		0 9
2	0 00	2734249 108	1889938 43	1 446740	1	200				
3	0 00	2793451 892	1934129 913	1 444294	1	200				
4	0 00	3378560 43	2296378 244	1 471256	1	204				
5	0 00	2653918 985	1828035 514	1 451787	1	201				
92	0 00	2964928 843	2012373 87	1 473349	1	204				
93	0 00	2765224 675	1873567 018	1 475914	1	204				
34	3 00	41734 873	1949325 843	0 021410	1	2 88	-4 0	2 82	-6 0	3 3
63	3 00	38459 642	1874588 567	0 020516	1	2 75	-8 3			
41	37 5	546433 315	2125988 722	0 257026	1	35 5	-5 3	34 7	-7 5	3 5
70	37 5	497916 307	2032539 407	0 244973	1	33 8	-9 9			
26	150	507718 003	1928020 381	0 263336	4	145	-3 3	141	-6 0	3 6
55	150	581629 396	2262020 993	0 257128	4	142	-5 3			
77	150	613912 739	2505190 809	0 245056	4	135	-10 0			
27	150	1093223 621	2032485 493	0 537875	2	149	-0 7	147	-2 0	1 8
56	150	1022454 217	1905363 415	0 536619	2	148	-1 3			
78	150	1107410 542	2122839 659	0 521665	2	144	-4 0			
48	150	1984342 262	1879225 563	1 055936	1	146	-2 7	144	-4 0	2 0
90	150	2037481 652	1985829 373	1 026010	1	142	-5 3			

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)
AAR - Concentration Found is Greater than 200 (Highest Standard)

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 38
Serum, Concentration of Cotinine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
01	N/A	5 / Day 1 0 125h	1384408 132	1997238 735	0 693161	1	95 9	20	05104620000069	AA97220-01 05104620000069 01 N/A Serum-1 5 / Day 1 125h
01	N/A	8 / Day 1 0 333h	1101400 624	2013322 029	0 547056	1	75 7	21	05104620000056	AA97220-01 05104620000056 01 N/A Serum-1 8 / Day 1 333h
01	N/A	9 / Day 1 0 5h	1634569 155	2053472 75	0 796002	1	110	24	05104620000009	AA97220-01 05104620000009 01 N/A Serum-1 9 / Day 1 5h
01	N/A	16 / Day 1 3h	1644896 033	1925976 153	0 854058	1	118	25	05104620000016	AA97220-01 05104620000016 01 N/A Serum-1 16 / Day 1 3h
01	N/A	16 / Day 1 3h	1385371 005	1910817 5	0 725015	1	100	23	05104620000032	AA97220-01 05104620000032 01 N/A Serum-1 16 / Day 1 3h
01	N/A	16 / Day 1 3h	1602724 365	2415899 265	0 663407	1	91 8	22	05104620000048	AA97220-01 05104620000048 01 N/A Serum-1 16 / Day 1 3h
02	N/A	8 / Day 1 0 333h	1794012 948	2239507 172	0 801075	1	111	32	05104620000088	AA97220-01 05104620000088 02 N/A Serum-1 8 / Day 1 333h
02	N/A	16 / Day 1 3h	1583767 554	1878739 715	0 842995	1	117	33	05104620000096	AA97220-01 05104620000096 02 N/A Serum-1 16 / Day 1 3h
02	N/A	16 / Day 1 3h	2224608 256	2287267 25	0 972605	1	135	31	05104620000112	AA97220-01 05104620000112 02 N/A Serum-1 16 / Day 1 3h
02	N/A	16 / Day 1 3h	1798322 299	1986900 997	0 905089	1	125	30	05104620000128	AA97220-01 05104620000128 02 N/A Serum-1 16 / Day 1 3h
02	N/A	16 / Day 1 3h	1277730 804	1965661 292	0 650026	1	89 9	29	05104620000144	AA97220-01 05104620000144 02 N/A Serum-1 16 / Day 1 3h
02	N/A	16 / Day 1 3h	1316538 628	1800617 823	0 731159	1	101	28	05104620000160	AA97220-01 05104620000160 02 N/A Serum-1 16 / Day 1 3h
03	N/A	5 / Day 1 0 125h	1975624 725	2259225 804	0 874470	2	242	38	05104620000181	AA97220-01 05104620000181 03 N/A Serum-1 5 / Day 1 125h
03	N/A	7 / Day 1 0 25h	2130755 094	2050981 124	1 038896	2	288	35	05104620000231	AA97220-01 05104620000231 03 N/A Serum-1 7 / Day 1 25h
03	N/A	16 / Day 1 3h	1779410 731	2034236 285	0 874732	2	242	39	05104620000192	AA97220-01 05104620000192 03 N/A Serum-1 16 / Day 1 3h
03	N/A	16 / Day 1 3h	1698582 677	2012560 86	0 843991	2	234	37	05104620000208	AA97220-01 05104620000208 03 N/A Serum-1 16 / Day 1 3h
03	N/A	16 / Day 1 3h	1875556 005	1951569 364	0 961050	2	266	36	05104620000240	AA97220-01 05104620000240 03 N/A Serum-1 16 / Day 1 3h
04	N/A	4 / Day 1 0 0833h	2252154 757	2324117 9	0 969036	1	134	40	05104620000308	AA97220-01 05104620000308 04 N/A Serum-1 4 / Day 1 0833h
04	N/A	6 / Day 1 0 1667h	1226308 49	2155334 464	0 568964	1	78 7	46	05104620000246	AA97220-01 05104620000246 04 N/A Serum-1 6 / Day 1 1667h
04	N/A	8 / Day 1 0 333h	1803568 516	2336773 891	0 771820	1	107	44	05104620000264	AA97220-01 05104620000264 04 N/A Serum-1 8 / Day 1 333h
04	N/A	9 / Day 1 0 5h	1331471 953	2269809 299	0 586601	2	162	42	05104620000297	AA97220-01 05104620000297 04 N/A Serum-1 9 / Day 1 5h
04	N/A	16 / Day 1 3h	817816 502	1901859 806	0 430009	1	59 4	47	05104620000256	AA97220-01 05104620000256 04 N/A Serum-1 16 / Day 1 3h
04	N/A	16 / Day 1 3h	1418408 806	1999695 741	0 709312	1	98 1	45	05104620000272	AA97220-01 05104620000272 04 N/A Serum-1 16 / Day 1 3h
04	N/A	16 / Day 1 3h	1195278 512	2104075 188	0 568078	2	157	43	05104620000304	AA97220-01 05104620000304 04 N/A Serum-1 16 / Day 1 3h
05	N/A	6 / Day 1 0 1667h	1810329 91	2321915 775	0 779671	2	216	49	05104620000374	AA97220-01 05104620000374 05 N/A Serum-1 6 / Day 1 1667h
05	N/A	9 / Day 1 0 5h	1550117 94	2284365 597	0 678577	2	188	51	05104620000361	AA97220-01 05104620000361 05 N/A Serum-1 9 / Day 1 5h
05	N/A	10 / Day 1 0 75h	1314432 69	2089354 456	0 629109	2	174	53	05104620000330	AA97220-01 05104620000330 05 N/A Serum-1 10 / Day 1 75h
05	N/A	16 / Day 1 3h	2763838 072	2391709 765	1 155591	1	160	54	05104620000336	AA97220-01 05104620000336 05 N/A Serum-1 16 / Day 1 3h
05	N/A	16 / Day 1 3h	2670183 495	2307085 422	1 157384	1	160	52	05104620000368	AA97220-01 05104620000368 05 N/A Serum-1 16 / Day 1 3h
05	N/A	16 / Day 1 3h	1292626 079	1814129 895	0 712532	2	197	50	05104620000384	AA97220-01 05104620000384 05 N/A Serum-1 16 / Day 1 3h
06	N/A	10 / Day 1 0 75h	1832699 513	2274573 01	0 805733	1	111	58	05104620000410	AA97220-01 05104620000410 06 N/A Serum-1 10 / Day 1 75h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
06	N/A	15 / Day 1 2 5h	1433854 788	1983721 175	0 722811	1	100	59	05104620000415	AA97220-01 05104620000415 06 N/A Serum-1 15 / Day 1 2 5h
06	N/A	16 / Day 1 3h	1710820 951	1954105 613	0 875501	1	121	57	05104620000464	AA97220-01 05104620000464 06 N/A Serum-1 16 / Day 1 3h
07	N/A	6 / Day 1 0 1667h	1431866 579	2090598 284	0 684908	1	94 7	60	05104620000550	AA97220-01 05104620000550 07 N/A Serum-1 6 / Day 1 1667h
07	N/A	16 / Day 1 3h	1369672 967	2172817 337	0 630367	1	87 2	61	05104620000560	AA97220-01 05104620000560 07 N/A Serum-1 16 / Day 1 3h
10	N/A	9 / Day 1 0 5h	2243745 126	1877232 572	1 195241	2	331	64	05104620000729	AA97220-01 05104620000729 10 N/A Serum-1 9 / Day 1 5h
10	N/A	10 / Day 1 0 75h	2144190 848	2277038 92	0 941658	2	261	62	05104620000746	AA97220-01 05104620000746 10 N/A Serum-1 10 / Day 1 75h
10	N/A	16 / Day 1 3h	2116219 097	2051055 667	1 031771	2	286	65	05104620000736	AA97220-01 05104620000736 10 N/A Serum-1 16 / Day 1 3h
11	N/A	8 / Day 1 0 333h	1538152 714	2322346 822	0 662327	2	183	68	05104620000840	AA97220-01 05104620000840 11 N/A Serum-1 8 / Day 1 333h
11	N/A	13 / Day 1 1 5h	1326890 01	2314585 234	0 573273	2	159	67	05104620000861	AA97220-01 05104620000861 11 N/A Serum-1 13 / Day 1 1 5h
11	N/A	16 / Day 1 3h	1244780 255	1985360 979	0 626979	2	173	69	05104620000848	AA97220-01 05104620000848 11 N/A Serum-1 16 / Day 1 3h
11	N/A	16 / Day 1 3h	1572532 822	1857385 349	0 846638	2	234	66	05104620000880	AA97220-01 05104620000880 11 N/A Serum-1 16 / Day 1 3h
12	N/A	4 / Day 1 0 0833h	2498206 059	2479243 871	1 007648	4	558	71	05104620000948	AA97220-01 05104620000948 12 N/A Serum-1 4 / Day 1 0 833h
12	N/A	8 / Day 1 0 333h	1600658 265	2015681 084	0 794103	4	439	72	05104620000936	AA97220-01 05104620000936 12 N/A Serum-1 8 / Day 1 333h
12	N/A	10 / Day 1 0 75h	2920699 837	2136454 671	1 367078	4	757	76	05104620000890	AA97220-01 05104620000890 12 N/A Serum-1 10 / Day 1 75h
12	N/A	16 / Day 1 3h	2877503 315	2283129 126	1 260333	4	698	79	05104620000896	AA97220-01 05104620000896 12 N/A Serum-1 16 / Day 1 3h
12	N/A	16 / Day 1 3h	2164406 612	2079710 709	1 040725	4	576	75	05104620000912	AA97220-01 05104620000912 12 N/A Serum-1 16 / Day 1 3h
12	N/A	16 / Day 1 3h	1971249 987	2461912 595	0 800699	4	443	74	05104620000928	AA97220-01 05104620000928 12 N/A Serum-1 16 / Day 1 3h
12	N/A	16 / Day 1 3h	1764492 367	2296063 107	0 768486	4	425	73	05104620000944	AA97220-01 05104620000944 12 N/A Serum-1 16 / Day 1 3h
13	N/A	7 / Day 1 0 25h	1908189 734	2459265 354	0 775919	1	107	82	05104620000983	AA97220-01 05104620000983 13 N/A Serum-1 7 / Day 1 25h
13	N/A	9 / Day 1 0 5h	1533234 082	1982110 752	0 773536	1	107	81	05104620001001	AA97220-01 05104620001001 13 N/A Serum-1 9 / Day 1 5h
13	N/A	10 / Day 1 0 75h	2224075 95	1882372 212	1 181528	1	163	84	05104620000970	AA97220-01 05104620000970 13 N/A Serum-1 10 / Day 1 75h
13	N/A	10 / Day 1 0 75h	1603186 811	2272169 351	0 705575	2	195	80	05104620001018	AA97220-01 05104620001018 13 N/A Serum-1 10 / Day 1 75h
13	N/A	16 / Day 1 3h	1766105 322	2477126 323	0 712965	1	98 6	83	05104620000992	AA97220-01 05104620000992 13 N/A Serum-1 16 / Day 1 3h
14	N/A	8 / Day 1 0 333h	2034279 42	2074318 537	0 980698	2	271	85	05104620001112	AA97220-01 05104620001112 14 N/A Serum-1 8 / Day 1 333h
14	N/A	9 / Day 1 0 5h	2019702 852	1938531 696	1 041872	2	288	87	05104620001081	AA97220-01 05104620001081 14 N/A Serum-1 9 / Day 1 5h
14	N/A	16 / Day 1 3h	1291241 001	1922240 988	0 671737	2	186	88	05104620001072	AA97220-01 05104620001072 14 N/A Serum-1 16 / Day 1 3h
14	N/A	16 / Day 1 3h	1862381 264	1953574 05	0 953320	2	264	86	05104620001120	AA97220-01 05104620001120 14 N/A Serum-1 16 / Day 1 3h
15	N/A	16 / Day 1 3h	1257604 085	1764347 056	0 712787	2	197	89	05104620001200	AA97220-01 05104620001200 15 N/A Serum-1 16 / Day 1 3h

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)
AAR - Concentration Found is Greater than 200 (Highest Standard)

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 39
 Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		0	2194146 819	0 000000	0 0280		0 0280	0 0
9	0 00		0	1935450 085	0 000000	0 0280			
10	1 00	1 00000	16467 455	2300001 7	0 007160	0 971	-2 9		
11	2 00	0 250000	36206 964	2353880 555	0 015382	2 05	2 5		
12	4 00	0 0625000	61741 007	1885986 775	0 032737	4 34	8 5		
13	8 00	0 0156250	128721 765	2215790 913	0 058093	7 68	-4 0		
14	16 0	0 00390625	236111 409	1963625 621	0 120243	15 9	-0 6		
15	40 0	0 000625000	713385 993	2431094 086	0 293442	38 7	-3 3		
16	80 0	0 000156250	1027588 227	1662049 614	0 618266	81 5	1 9		
17	160	0 0000390625	2593865 684	2141503 237	1 211236	160	0 0		
18	200	0 0000250000	2731537 696	1834267 509	1 489171	196	-2 0		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:

Slope = 0 00759048648

Intercept = -0 000212390581

R-Squared = 0 9980

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 39
Serum, Concentration of Cotinine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	2931984 492	1948021 09	1 505109	1	198		199		1 2
2	0 00	3227991 105	2122456 051	1 520875	1	200				
3	0 00	3102231 041	2080330 796	1 491220	1	196				
4	0 00	3169398 662	2059680 826	1 538781	1	203				
5	0 00	2748548 939	1822579 31	1 508055	1	199				
71	0 00	2546693 648	1679812 014	1 516059	1	200				
72	0 00	2625073 574	1764592 209	1 487638	1	196				
30	3 00	37921 154	1699288 732	0 022316	1	2 97	-1 0	2 95	-1 7	1 0
51	3 00	40912 325	1855109 742	0 022054	1	2 93	-2 3			
35	37 5	465354 007	1799562 17	0 258593	1	34 1	-9 1	34 3	-8 5	0 6
56	37 5	470947 782	1805300 525	0 260869	1	34 4	-8 3			
24	150	387069 446	1862429 394	0 207830	5	137	-8 7	140	-6 7	2 5
45	150	364986 899	1672859 363	0 218181	5	144	-4 0			
61	150	359347 176	1687370 601	0 212963	5	140	-6 7			
25	150	1020627 722	1919150 464	0 531812	2	140	-6 7	139	-7 3	1 1
46	150	927257 957	1783720 483	0 519845	2	137	-8 7			
62	150	764099 159	1450747 163	0 526694	2	139	-7 3			
40	150	1818642 38	1715853 351	1 059905	1	140	-6 7	136	-9 3	4 2
69	150	1647574 687	1640822 27	1 004115	1	132	-12 0			

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)
AAR - Concentration Found is Greater than 200 (Highest Standard)

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 39
Serum, Concentration of Cotinine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
13	N/A	1 / Day 1 -0 0333h	537164 721	1844762 482	0 291184	5	192	63	05104620001009	AA97220-01 05104620001009 13 N/A Serum-1 1 / Day 1 - 0333h
13	N/A	2 / Day 1 0h	465888 231	1613931 8	0 288667	5	190	64	05104620001010	AA97220-01 05104620001010 13 N/A Serum-1 2 / Day 1 0h
13	N/A	3 / Day 1 0 05h	447661 625	1598434 87	0 280062	5	185	65	05104620001011	AA97220-01 05104620001011 13 N/A Serum-1 3 / Day 1 05h
13	N/A	4 / Day 1 0 0833h	528190 613	1797924 354	0 293778	5	194	66	05104620001012	AA97220-01 05104620001012 13 N/A Serum-1 4 / Day 1 0833h
13	N/A	6 / Day 1 0 1667h	562789 71	1936246 137	0 290660	5	192	68	05104620001014	AA97220-01 05104620001014 13 N/A Serum-1 6 / Day 1 1667h
13	N/A	6 / Day 1 0 1667h	0	0	*N/A	1	*BLQ<(1 00)	67	05104620001030	AA97220-01 05104620001030 13 N/A Serum-1 6 / Day 1 1667h
14	N/A	16 / Day 1 3h	3380093 049	1928358 124	*1 752835	1	*AAR>(200)	39	05104620001088	AA97220-01 05104620001088 14 N/A Serum-1 16 / Day 1 3h
15	N/A	10 / Day 1 0 75h	1395027 851	1884879 265	*0 740115	2	*195	23	05104620001146	AA97220-01 05104620001146 15 N/A Serum-1 10 / Day 1 75h
15	N/A	10 / Day 1 0 75h	1264252 554	1763305 094	*0 716979	2	*189	22	05104620001162	AA97220-01 05104620001162 15 N/A Serum-1 10 / Day 1 75h
15	N/A	10 / Day 1 0 75h	1575487 183	1618355 714	*0 973511	2	*257	20	05104620001178	AA97220-01 05104620001178 15 N/A Serum-1 10 / Day 1 75h
15	N/A	16 / Day 1 3h	1226115 527	1632897 339	*0 750883	2	*198	27	05104620001136	AA97220-01 05104620001136 15 N/A Serum-1 16 / Day 1 3h
15	N/A	16 / Day 1 3h	2432516 091	1723852 512	*1 411093	1	*186	26	05104620001152	AA97220-01 05104620001152 15 N/A Serum-1 16 / Day 1 3h
15	N/A	16 / Day 1 3h	1651782 699	1913997 812	*0 863001	2	*227	21	05104620001184	AA97220-01 05104620001184 15 N/A Serum-1 16 / Day 1 3h
16	N/A	4 / Day 1 0 0833h	1155003 466	1750579 473	*0 659784	2	*174	28	05104620001268	AA97220-01 05104620001268 16 N/A Serum-1 4 / Day 1 0833h
16	N/A	8 / Day 1 0 333h	1079491 84	1656041 715	*0 651851	2	*172	29	05104620001256	AA97220-01 05104620001256 16 N/A Serum-1 8 / Day 1 333h
16	N/A	9 / Day 1 0 5h	1429262 537	1951272 777	*0 732477	2	*193	32	05104620001225	AA97220-01 05104620001225 16 N/A Serum-1 9 / Day 1 5h
16	N/A	16 / Day 1 3h	1192243 723	1934611 28	*0 616270	2	*162	33	05104620001232	AA97220-01 05104620001232 16 N/A Serum-1 16 / Day 1 3h
16	N/A	16 / Day 1 3h	1690315 07	1609632 769	*1 050125	1	*138	31	05104620001248	AA97220-01 05104620001248 16 N/A Serum-1 16 / Day 1 3h
17	N/A	1 / Day 1 -0 0333h	729806 302	2162271 749	0 337518	5	222	41	05104620001281	AA97220-01 05104620001281 17 N/A Serum-1 1 / Day 1 - 0333h
17	N/A	2 / Day 1 0h	602430 735	1729301 806	0 348366	5	230	42	05104620001282	AA97220-01 05104620001282 17 N/A Serum-1 2 / Day 1 0h
17	N/A	3 / Day 1 0 05h	561450 259	1517832 354	0 369903	5	244	43	05104620001283	AA97220-01 05104620001283 17 N/A Serum-1 3 / Day 1 05h
17	N/A	4 / Day 1 0 0833h	670821 359	1938323 308	0 346083	5	228	44	05104620001284	AA97220-01 05104620001284 17 N/A Serum-1 4 / Day 1 0833h
17	N/A	5 / Day 1 0 125h	525549 254	1530050 25	0 343485	5	226	47	05104620001285	AA97220-01 05104620001285 17 N/A Serum-1 5 / Day 1 125h
17	N/A	6 / Day 1 0 1667h	572788 15	1688413 023	0 339246	5	224	48	05104620001286	AA97220-01 05104620001286 17 N/A Serum-1 6 / Day 1 1667h
17	N/A	7 / Day 1 0 25h	644840 582	1913479 991	0 336999	5	222	49	05104620001287	AA97220-01 05104620001287 17 N/A Serum-1 7 / Day 1 25h
17	N/A	8 / Day 1 0 333h	525235 572	1560408 056	0 336601	5	222	50	05104620001288	AA97220-01 05104620001288 17 N/A Serum-1 8 / Day 1 333h
17	N/A	9 / Day 1 0 5h	617095 681	1710428 294	0 360784	5	238	52	05104620001289	AA97220-01 05104620001289 17 N/A Serum-1 9 / Day 1 5h
17	N/A	9 / Day 1 0 5h	1846509 479	1899032 534	*0 972342	2	*256	37	05104620001305	AA97220-01 05104620001305 17 N/A Serum-1 9 / Day 1 5h
17	N/A	10 / Day 1 0 75h	645312 235	1858187 434	0 347280	5	229	53	05104620001290	AA97220-01 05104620001290 17 N/A Serum-1 10 / Day 1 75h
17	N/A	11 / Day 1 1h	612575 858	1718663 391	0 356426	5	235	54	05104620001291	AA97220-01 05104620001291 17 N/A Serum-1 11 / Day 1 1h
17	N/A	12 / Day 1 1 25h	539305 286	1670606 155	0 322820	5	213	55	05104620001292	AA97220-01 05104620001292 17 N/A Serum-1 12 / Day 1 1 25h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
17	N/A	13 / Day 1 1 5h	688082 712	2088332 075	0 329489	5	217	57	05104620001293	AA97220-01 05104620001293 17 N/A Serum-1 13 / Day 1 1 5h
17	N/A	14 / Day 1 2h	526042 921	1547351 224	0 339963	5	224	58	05104620001294	AA97220-01 05104620001294 17 N/A Serum-1 14 / Day 1 2h
17	N/A	15 / Day 1 2 5h	566312 846	1743213 501	0 324867	5	214	59	05104620001295	AA97220-01 05104620001295 17 N/A Serum-1 15 / Day 1 2 5h
17	N/A	16 / Day 1 3h	574048 882	1676942 116	0 342319	5	226	60	05104620001296	AA97220-01 05104620001296 17 N/A Serum-1 16 / Day 1 3h
17	N/A	16 / Day 1 3h	1588422 703	1846447 626	*0 860259	2	*227	38	05104620001312	AA97220-01 05104620001312 17 N/A Serum-1 16 / Day 1 3h
17	N/A	16 / Day 1 3h	1294535 229	1670303 687	*0 775030	2	*204	36	05104620001328	AA97220-01 05104620001328 17 N/A Serum-1 16 / Day 1 3h
17	N/A	16 / Day 1 3h	1536454 409	2041719 489	*0 752530	2	*198	34	05104620001360	AA97220-01 05104620001360 17 N/A Serum-1 16 / Day 1 3h

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)

AAR - Concentration Found is Greater than 200 (Highest Standard)

* - Sample Rejected

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 1
Serum, Concentration of Nicotine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		0	68949 257	0 000000	-0 0187		-0 0187	0 0
9	0 00		0	85944 134	0 000000	-0 0187			
10	0 500	4 00000	28262 673	79135 883	0 357141	0 487	-2 6		
11	1 00	1 00000	54814 092	74179 228	0 738941	1 03	3 0		
12	2 00	0 250000	114936 688	74874 159	1 535065	2 16	8 0		
13	4 00	0 0625000	240196 084	87831 977	2 734723	3 85	-3 8		
14	8 00	0 0156250	457452 796	81160 798	5 636376	7 96	-0 5		
15	10 0	0 0100000	493597 94	73950 405	6 674716	9 43	-5 7		
16	20 0	0 00250000	1119522 289	79578 16	14 068210	19 9	-0 5		
17	40 0	0 000625000	2427027 24	79879 467	30 383618	43 0	7 5		
18	50 0	0 000400000	2472519 872	73865 137	33 473435	47 4	-5 2		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:

Slope = 0 706122544

Intercept = 0 0132239810

R-Squared = 0 9965

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)

AAR - Concentration Found is Greater than 50 0 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 1
 Serum, Concentration of Nicotine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	2777623 697	77993 47	35 613542	1	50 4		49 4		2 1
2	0 00	2411769 164	70517 697	34 200907	1	48 4				
3	0 00	2412124 409	69681 263	34 616543	1	49 0				
4	0 00	2461017 98	71226 802	34 551853	1	48 9				
5	0 00	2551616 19	74165 767	34 404231	1	48 7				
91	0 00	2398061 902	66119 916	36 268375	1	51 3				
92	0 00	2515935 327	72285 64	34 805465	1	49 3				
30	1 50	74045 283	66532 78	1 112914	1	1 56	4 0	1 57	4 7	0 9
63	1 50	76675 01	67877 123	1 129615	1	1 58	5 3			
41	8 00	396972 022	69890 125	5 679944	1	8 03	0 4	8 07	0 9	0 6
74	8 00	400145 294	69825 016	5 730687	1	8 10	1 3			
52	37 5	1978776 305	70823 502	27 939543	1	39 5	5 3	39 3	4 8	0 9
89	37 5	1769771 271	64157 881	27 584628	1	39 0	4 0			

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)
 AAR - Concentration Found is Greater than 50 0 (Highest Standard)

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 1
Serum, Concentration of Nicotine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
01	N/A	1 / Day 1 -0 0333h	31018 35	69647 91	0 445359	1	0 612	23	05104620000017	AA97220-01 05104620000017 01 N/A Serum-1 1 / Day 1 - 0333h
01	N/A	1 / Day 1 -0 0333h	29482 331	68712 49	0 429068	1	0 589	21	05104620000033	AA97220-01 05104620000033 01 N/A Serum-1 1 / Day 1 - 0333h
01	N/A	1 / Day 1 -0 0333h	20375 908	66493 295	0 306436	1	BLQ<(0 500)	20	05104620000049	AA97220-01 05104620000049 01 N/A Serum-1 1 / Day 1 - 0333h
01	N/A	1 / Day 1 -0 0333h	28301 967	69543 83	0 406966	1	0 558	22	05104620000065	AA97220-01 05104620000065 01 N/A Serum-1 1 / Day 1 - 0333h
01	N/A	2 / Day 1 0h	24087 372	61721 817	0 390257	1	0 534	26	05104620000018	AA97220-01 05104620000018 01 N/A Serum-1 2 / Day 1 0h
01	N/A	2 / Day 1 0h	26366 693	63555 42	0 414861	1	0 569	25	05104620000034	AA97220-01 05104620000034 01 N/A Serum-1 2 / Day 1 0h
01	N/A	2 / Day 1 0h	20410 053	63353 203	0 322163	1	BLQ<(0 500)	27	05104620000050	AA97220-01 05104620000050 01 N/A Serum-1 2 / Day 1 0h
01	N/A	2 / Day 1 0h	117672 829	66771 808	1 762313	1	2 48	24	05104620000066	AA97220-01 05104620000066 01 N/A Serum-1 2 / Day 1 0h
01	N/A	3 / Day 1 0 05h	23777 942	62667 513	0 379430	1	0 519	29	05104620000019	AA97220-01 05104620000019 01 N/A Serum-1 3 / Day 1 05h
01	N/A	3 / Day 1 0 05h	27074 817	64139 55	0 422124	1	0 579	32	05104620000035	AA97220-01 05104620000035 01 N/A Serum-1 3 / Day 1 05h
01	N/A	3 / Day 1 0 05h	29017 648	63691 438	0 455597	1	0 626	28	05104620000051	AA97220-01 05104620000051 01 N/A Serum-1 3 / Day 1 05h
01	N/A	3 / Day 1 0 05h	553727 569	66548 417	8 320672	1	11 8	31	05104620000067	AA97220-01 05104620000067 01 N/A Serum-1 3 / Day 1 05h
01	N/A	4 / Day 1 0 0833h	28140 152	61314 487	0 458948	1	0 631	34	05104620000020	AA97220-01 05104620000020 01 N/A Serum-1 4 / Day 1 0833h
01	N/A	4 / Day 1 0 0833h	61400 552	72228 827	0 850084	1	1 19	33	05104620000036	AA97220-01 05104620000036 01 N/A Serum-1 4 / Day 1 0833h
01	N/A	4 / Day 1 0 0833h	43444 836	63545 952	0 683676	1	0 949	36	05104620000052	AA97220-01 05104620000052 01 N/A Serum-1 4 / Day 1 0833h
01	N/A	4 / Day 1 0 0833h	644146 29	60381 815	10 667886	1	15 1	35	05104620000068	AA97220-01 05104620000068 01 N/A Serum-1 4 / Day 1 0833h
01	N/A	5 / Day 1 0 125h	45418 194	71725 112	0 633226	1	0 878	38	05104620000021	AA97220-01 05104620000021 01 N/A Serum-1 5 / Day 1 125h
01	N/A	5 / Day 1 0 125h	85446 195	62627 577	1 364354	1	1 91	39	05104620000037	AA97220-01 05104620000037 01 N/A Serum-1 5 / Day 1 125h
01	N/A	5 / Day 1 0 125h	72539 88	67430 865	1 075767	1	1 50	40	05104620000053	AA97220-01 05104620000053 01 N/A Serum-1 5 / Day 1 125h
01	N/A	5 / Day 1 0 125h	1018107 723	65772 185	15 479305	1	21 9	37	05104620000069	AA97220-01 05104620000069 01 N/A Serum-1 5 / Day 1 125h
01	N/A	6 / Day 1 0 1667h	43788 405	66242 529	0 661032	1	0 917	45	05104620000022	AA97220-01 05104620000022 01 N/A Serum-1 6 / Day 1 1667h
01	N/A	6 / Day 1 0 1667h	145091 283	70599 8	2 055123	1	2 89	44	05104620000038	AA97220-01 05104620000038 01 N/A Serum-1 6 / Day 1 1667h
01	N/A	6 / Day 1 0 1667h	78277 067	69387 478	1 128115	1	1 58	42	05104620000054	AA97220-01 05104620000054 01 N/A Serum-1 6 / Day 1 1667h
01	N/A	6 / Day 1 0 1667h	1006873 821	66315 87	15 182999	1	21 5	43	05104620000070	AA97220-01 05104620000070 01 N/A Serum-1 6 / Day 1 1667h
01	N/A	7 / Day 1 0 25h	43434 555	54880 453	0 791439	1	1 10	48	05104620000023	AA97220-01 05104620000023 01 N/A Serum-1 7 / Day 1 25h
01	N/A	7 / Day 1 0 25h	137266 968	70198 317	1 955417	1	2 75	47	05104620000039	AA97220-01 05104620000039 01 N/A Serum-1 7 / Day 1 25h
01	N/A	7 / Day 1 0 25h	73653 542	72439 582	1 016758	1	1 42	46	05104620000055	AA97220-01 05104620000055 01 N/A Serum-1 7 / Day 1 25h
01	N/A	7 / Day 1 0 25h	856587 368	67510 762	12 688160	1	18 0	49	05104620000071	AA97220-01 05104620000071 01 N/A Serum-1 7 / Day 1 25h
01	N/A	8 / Day 1 0 333h	59159 513	71041 403	0 832747	1	1 16	50	05104620000024	AA97220-01 05104620000024 01 N/A Serum-1 8 / Day 1 333h
01	N/A	8 / Day 1 0 333h	145262 134	69443 632	2 091799	1	2 94	54	05104620000040	AA97220-01 05104620000040 01 N/A Serum-1 8 / Day 1 333h
01	N/A	8 / Day 1 0 333h	58909 275	64555 6	0 912535	1	1 27	53	05104620000056	AA97220-01 05104620000056 01 N/A Serum-1 8 / Day 1 333h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
01	N/A	8 / Day 1 0 333h	822217 725	70045 89	11 738272	1	16 6	51	05104620000072	AA97220-01 05104620000072 01 N/A Serum-1 8 / Day 1 333h
01	N/A	9 / Day 1 0 5h	58134 465	64050 095	0 907641	1	1 27	56	05104620000025	AA97220-01 05104620000025 01 N/A Serum-1 9 / Day 1 5h
01	N/A	9 / Day 1 0 5h	130765 463	70002 072	1 868023	1	2 63	55	05104620000041	AA97220-01 05104620000041 01 N/A Serum-1 9 / Day 1 5h
01	N/A	9 / Day 1 0 5h	57088 697	63989 172	0 892162	1	1 24	57	05104620000057	AA97220-01 05104620000057 01 N/A Serum-1 9 / Day 1 5h
01	N/A	9 / Day 1 0 5h	619704 794	64377 47	9 626113	1	13 6	58	05104620000073	AA97220-01 05104620000073 01 N/A Serum-1 9 / Day 1 5h
01	N/A	10 / Day 1 0 75h	83653 332	71870 082	1 163952	1	1 63	61	05104620000026	AA97220-01 05104620000026 01 N/A Serum-1 10 / Day 1 75h
01	N/A	10 / Day 1 0 75h	118179 984	68822 138	1 717180	1	2 41	60	05104620000042	AA97220-01 05104620000042 01 N/A Serum-1 10 / Day 1 75h
01	N/A	10 / Day 1 0 75h	62041 592	64712 502	0 958727	1	1 34	59	05104620000058	AA97220-01 05104620000058 01 N/A Serum-1 10 / Day 1 75h
01	N/A	10 / Day 1 0 75h	466438 669	67365 895	6 923959	1	9 79	62	05104620000074	AA97220-01 05104620000074 01 N/A Serum-1 10 / Day 1 75h
01	N/A	11 / Day 1 1 h	85060 282	68501 202	1 241734	1	1 74	64	05104620000027	AA97220-01 05104620000027 01 N/A Serum-1 11 / Day 1 1h
01	N/A	11 / Day 1 1 h	103781 583	69765 39	1 487580	1	2 09	67	05104620000043	AA97220-01 05104620000043 01 N/A Serum-1 11 / Day 1 1h
01	N/A	11 / Day 1 1 h	69938 664	71543 045	0 977575	1	1 37	66	05104620000059	AA97220-01 05104620000059 01 N/A Serum-1 11 / Day 1 1h
01	N/A	11 / Day 1 1 h	453772 945	73039 785	6 212682	1	8 78	65	05104620000075	AA97220-01 05104620000075 01 N/A Serum-1 11 / Day 1 1h
01	N/A	12 / Day 1 1 25h	95836 881	73258 433	1 308203	1	1 83	69	05104620000028	AA97220-01 05104620000028 01 N/A Serum-1 12 / Day 1 1 25h
01	N/A	12 / Day 1 1 25h	94741 166	70493 66	1 343967	1	1 88	68	05104620000044	AA97220-01 05104620000044 01 N/A Serum-1 12 / Day 1 1 25h
01	N/A	12 / Day 1 1 25h	64272 626	68390 357	0 939791	1	1 31	71	05104620000060	AA97220-01 05104620000060 01 N/A Serum-1 12 / Day 1 1 25h
01	N/A	12 / Day 1 1 25h	385464 409	72316 636	5 330231	1	7 53	70	05104620000076	AA97220-01 05104620000076 01 N/A Serum-1 12 / Day 1 1 25h
01	N/A	13 / Day 1 1 5h	82898 127	75765 057	1 094147	1	1 53	72	05104620000029	AA97220-01 05104620000029 01 N/A Serum-1 13 / Day 1 1 5h
01	N/A	13 / Day 1 1 5h	77825 727	67406 335	1 154576	1	1 62	76	05104620000045	AA97220-01 05104620000045 01 N/A Serum-1 13 / Day 1 1 5h
01	N/A	13 / Day 1 1 5h	58490 687	65238 459	0 896568	1	1 25	73	05104620000061	AA97220-01 05104620000061 01 N/A Serum-1 13 / Day 1 1 5h
01	N/A	13 / Day 1 1 5h	299791 001	63670 465	4 708478	1	6 65	75	05104620000077	AA97220-01 05104620000077 01 N/A Serum-1 13 / Day 1 1 5h
01	N/A	14 / Day 1 2 h	79087 515	65037 758	1 216025	1	1 70	78	05104620000030	AA97220-01 05104620000030 01 N/A Serum-1 14 / Day 1 2h
01	N/A	14 / Day 1 2 h	70018 105	73571 66	0 951699	1	1 33	79	05104620000046	AA97220-01 05104620000046 01 N/A Serum-1 14 / Day 1 2h
01	N/A	14 / Day 1 2 h	48359 299	62789 134	0 770186	1	1 07	77	05104620000062	AA97220-01 05104620000062 01 N/A Serum-1 14 / Day 1 2h
01	N/A	14 / Day 1 2 h	258515 436	72126 893	3 584175	1	5 06	80	05104620000078	AA97220-01 05104620000078 01 N/A Serum-1 14 / Day 1 2h
01	N/A	15 / Day 1 2 5h	56490 317	69066 482	0 817912	1	1 14	81	05104620000031	AA97220-01 05104620000031 01 N/A Serum-1 15 / Day 1 2 5h
01	N/A	15 / Day 1 2 5h	43191 804	55606 221	0 776744	1	1 08	84	05104620000047	AA97220-01 05104620000047 01 N/A Serum-1 15 / Day 1 2 5h
01	N/A	15 / Day 1 2 5h	41888 679	72278 672	0 579544	1	0 802	83	05104620000063	AA97220-01 05104620000063 01 N/A Serum-1 15 / Day 1 2 5h
01	N/A	15 / Day 1 2 5h	211807 482	68440 208	3 094781	1	4 36	82	05104620000079	AA97220-01 05104620000079 01 N/A Serum-1 15 / Day 1 2 5h
01	N/A	16 / Day 1 3 h	52588 903	69673 322	0 754793	1	1 05	85	05104620000032	AA97220-01 05104620000032 01 N/A Serum-1 16 / Day 1 3h
01	N/A	16 / Day 1 3 h	45339 275	66333 295	0 683507	1	0 949	87	05104620000048	AA97220-01 05104620000048 01 N/A Serum-1 16 / Day 1 3h
01	N/A	16 / Day 1 3 h	32469 623	66556 585	0 487850	1	0 672	88	05104620000064	AA97220-01 05104620000064 01 N/A Serum-1 16 / Day 1 3h
01	N/A	16 / Day 1 3 h	162129 408	64144 585	2 527562	1	3 56	86	05104620000080	AA97220-01 05104620000080 01 N/A Serum-1 16 / Day 1 3h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0.500 (Lowest Standard)

AAR - Concentration Found is Greater than 50.0 (Highest Standard)

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 2
 Serum, Concentration of Nicotine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		0	63327 103	0 000000	0 00410		0 00410	0 0
9	0 00		0	61714 627	0 000000	0 00410			
10	0 500	4 00000	23606 378	66701 552	0 353910	0 498	-0 4		
11	1 00	1 00000	50608 73	70295 22	0 719946	1 01	1 0		
12	2 00	0 250000	83572 78	58284 852	1 433868	2 01	0 5		
13	4 00	0 0625000	174857 633	62470 553	2 799041	3 91	-2 3		
14	8 00	0 0156250	365936 317	64076 863	5 710896	7 98	-0 3		
15	10 0	0 0100000	459188 908	63911 57	7 184754	10 0	0 0		
16	20 0	0 00250000	904779 163	61862 48	14 625653	20 4	2 0		
17	40 0	0 000625000	1851494 735	63386 98	29 209386	40 8	2 0		
18	50 0	0 000400000	1990892 25	57330 732	34 726440	48 5	-3 0		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:

Slope = 0 716089655

Intercept = -0 00293934828

R-Squared = 0 9996

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)

AAR - Concentration Found is Greater than 50 0 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 2
Serum, Concentration of Nicotine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	2427455 433	69248 302	35 054368	1	49 0		49 0		1 9
2	0 00	2137861 143	62166 165	34 389465	1	48 0				
3	0 00	2300298 94	64421 725	35 706882	1	49 9				
4	0 00	2057947 612	56963 348	36 127575	1	50 5				
5	0 00	2324014 875	67175 472	34 596182	1	48 3				
91	0 00	1882766 861	53891 075	34 936524	1	48 8				
92	0 00	1851215 178	53367 235	34 688235	1	48 4				
30	1 50	61930 92	59654 455	1 038161	1	1 45	-3 3	1 51	0 7	5 6
63	1 50	72664 105	65001 121	1 117890	1	1 57	4 7			
41	8 00	365274 704	65646 993	5 564226	1	7 77	-2 9	7 81	-2 4	0 6
74	8 00	304318 307	54203 382	5 614379	1	7 84	-2 0			
52	37 5	1720300 469	60539 178	28 416317	1	39 7	5 9	39 0	4 0	2 5
89	37 5	1397374 28	50956 34	27 422972	1	38 3	2 1			

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)
AAR - Concentration Found is Greater than 50 0 (Highest Standard)

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 2
Serum, Concentration of Nicotine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
01	N/A	1 / Day 1 -0 0333h	26196 347	62980 895	0 415941	1	0 585	20	05104620000001	AA97220-01 05104620000001 01 N/A Serum-1 1 / Day 1 - 0333h
01	N/A	2 / Day 1 0h	26950 205	64128 987	0 420250	1	0 591	21	05104620000002	AA97220-01 05104620000002 01 N/A Serum-1 2 / Day 1 0h
01	N/A	3 / Day 1 0 05h	23539 263	58413 025	0 402980	1	0 567	22	05104620000003	AA97220-01 05104620000003 01 N/A Serum-1 3 / Day 1 05h
01	N/A	4 / Day 1 0 0833h	32236 858	60902 394	0 529320	1	0 743	23	05104620000004	AA97220-01 05104620000004 01 N/A Serum-1 4 / Day 1 0833h
01	N/A	5 / Day 1 0 125h	39158 487	56734 168	0 690210	1	0 968	24	05104620000005	AA97220-01 05104620000005 01 N/A Serum-1 5 / Day 1 125h
01	N/A	6 / Day 1 0 1667h	77097 605	63300 991	1 217953	1	1 70	25	05104620000006	AA97220-01 05104620000006 01 N/A Serum-1 6 / Day 1 1667h
01	N/A	7 / Day 1 0 25h	118488	57353 34	2 065930	1	2 89	26	05104620000007	AA97220-01 05104620000007 01 N/A Serum-1 7 / Day 1 25h
01	N/A	8 / Day 1 0 333h	165949 163	63553 342	2 611179	1	3 65	27	05104620000008	AA97220-01 05104620000008 01 N/A Serum-1 8 / Day 1 333h
01	N/A	9 / Day 1 0 5h	185479 95	57702 255	3 214432	1	4 49	28	05104620000009	AA97220-01 05104620000009 01 N/A Serum-1 9 / Day 1 5h
01	N/A	10 / Day 1 0 75h	178779 02	64035 943	2 791854	1	3 90	29	05104620000010	AA97220-01 05104620000010 01 N/A Serum-1 10 / Day 1 75h
01	N/A	11 / Day 1 1h	159185 282	53718 059	2 963348	1	4 14	31	05104620000011	AA97220-01 05104620000011 01 N/A Serum-1 11 / Day 1 1h
01	N/A	12 / Day 1 1 25h	182868 762	64974 071	2 814488	1	3 93	32	05104620000012	AA97220-01 05104620000012 01 N/A Serum-1 12 / Day 1 1 25h
01	N/A	13 / Day 1 1 5h	136471 202	57915 408	2 356389	1	3 29	33	05104620000013	AA97220-01 05104620000013 01 N/A Serum-1 13 / Day 1 1 5h
01	N/A	14 / Day 1 2h	113911 736	60897 376	1 870552	1	2 62	34	05104620000014	AA97220-01 05104620000014 01 N/A Serum-1 14 / Day 1 2h
01	N/A	15 / Day 1 2 5h	90521 678	59816 597	1 513320	1	2 12	35	05104620000015	AA97220-01 05104620000015 01 N/A Serum-1 15 / Day 1 2 5h
01	N/A	16 / Day 1 3h	75742 902	58290 878	1 299395	1	1 82	36	05104620000016	AA97220-01 05104620000016 01 N/A Serum-1 16 / Day 1 3h
02	N/A	1 / Day 1 -0 0333h	27165 905	57923 845	0 468993	1	0 659	39	05104620000113	AA97220-01 05104620000113 02 N/A Serum-1 1 / Day 1 - 0333h
02	N/A	1 / Day 1 -0 0333h	15495 16	57943 843	0 267417	1	BLQ<(0 500)	37	05104620000129	AA97220-01 05104620000129 02 N/A Serum-1 1 / Day 1 - 0333h
02	N/A	1 / Day 1 -0 0333h	18189 658	58025 023	0 313480	1	BLQ<(0 500)	38	05104620000145	AA97220-01 05104620000145 02 N/A Serum-1 1 / Day 1 - 0333h
02	N/A	2 / Day 1 0h	26585 435	64052 522	0 415057	1	0 584	43	05104620000114	AA97220-01 05104620000114 02 N/A Serum-1 2 / Day 1 0h
02	N/A	2 / Day 1 0h	12896 253	52953 475	0 243539	1	BLQ<(0 500)	42	05104620000130	AA97220-01 05104620000130 02 N/A Serum-1 2 / Day 1 0h
02	N/A	2 / Day 1 0h	17332 732	52998 753	0 327040	1	BLQ<(0 500)	40	05104620000146	AA97220-01 05104620000146 02 N/A Serum-1 2 / Day 1 0h
02	N/A	3 / Day 1 0 05h	25103 607	56970 658	0 440641	1	0 619	44	05104620000115	AA97220-01 05104620000115 02 N/A Serum-1 3 / Day 1 05h
02	N/A	3 / Day 1 0 05h	19392 135	59006 936	0 328642	1	BLQ<(0 500)	46	05104620000131	AA97220-01 05104620000131 02 N/A Serum-1 3 / Day 1 05h
02	N/A	3 / Day 1 0 05h	346555 112	58466 003	5 927464	1	8 28	45	05104620000147	AA97220-01 05104620000147 02 N/A Serum-1 3 / Day 1 05h
02	N/A	4 / Day 1 0 0833h	31637 47	67826 123	0 466450	1	0 655	47	05104620000116	AA97220-01 05104620000116 02 N/A Serum-1 4 / Day 1 0833h
02	N/A	4 / Day 1 0 0833h	26874 053	60368 41	0 445167	1	0 626	48	05104620000132	AA97220-01 05104620000132 02 N/A Serum-1 4 / Day 1 0833h
02	N/A	4 / Day 1 0 0833h	639955 226	52541 646	12 179962	1	17 0	49	05104620000148	AA97220-01 05104620000148 02 N/A Serum-1 4 / Day 1 0833h
02	N/A	5 / Day 1 0 125h	35293 552	57046 962	0 618675	1	0 868	53	05104620000117	AA97220-01 05104620000117 02 N/A Serum-1 5 / Day 1 125h
02	N/A	5 / Day 1 0 125h	56981 38	64953 413	0 877265	1	1 23	50	05104620000133	AA97220-01 05104620000133 02 N/A Serum-1 5 / Day 1 125h
02	N/A	5 / Day 1 0 125h	795272 293	55729 7	14 270170	1	19 9	51	05104620000149	AA97220-01 05104620000149 02 N/A Serum-1 5 / Day 1 125h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
02	N/A	6 / Day 1 0 1667h	42582 946	53132 667	0 801446	1	1 12	56	05104620000118	AA97220-01 05104620000118 02 N/A Serum-1 6 / Day 1 1667h
02	N/A	6 / Day 1 0 1667h	67136 015	51553 242	1 302266	1	1 82	55	05104620000134	AA97220-01 05104620000134 02 N/A Serum-1 6 / Day 1 1667h
02	N/A	6 / Day 1 0 1667h	473237 391	50889 988	9 299224	1	13 0	54	05104620000150	AA97220-01 05104620000150 02 N/A Serum-1 6 / Day 1 1667h
02	N/A	7 / Day 1 0 25h	52556 018	54826 865	0 958581	1	1 34	58	05104620000119	AA97220-01 05104620000119 02 N/A Serum-1 7 / Day 1 25h
02	N/A	7 / Day 1 0 25h	62015 16	52792 998	1 174685	1	1 64	59	05104620000135	AA97220-01 05104620000135 02 N/A Serum-1 7 / Day 1 25h
02	N/A	7 / Day 1 0 25h	394097 036	54418 98	7 241904	1	10 1	57	05104620000151	AA97220-01 05104620000151 02 N/A Serum-1 7 / Day 1 25h
02	N/A	8 / Day 1 0 333h	84434 138	63386 75	1 332047	1	1 86	61	05104620000120	AA97220-01 05104620000120 02 N/A Serum-1 8 / Day 1 333h
02	N/A	8 / Day 1 0 333h	64245 203	57609 788	1 115179	1	1 56	60	05104620000136	AA97220-01 05104620000136 02 N/A Serum-1 8 / Day 1 333h
02	N/A	8 / Day 1 0 333h	322561 903	57186 218	5 640553	1	7 88	62	05104620000152	AA97220-01 05104620000152 02 N/A Serum-1 8 / Day 1 333h
02	N/A	9 / Day 1 0 5h	77180 755	53007 485	1 456035	1	2 04	64	05104620000121	AA97220-01 05104620000121 02 N/A Serum-1 9 / Day 1 5h
02	N/A	9 / Day 1 0 5h	61067 987	55330 463	1 103696	1	1 55	66	05104620000137	AA97220-01 05104620000137 02 N/A Serum-1 9 / Day 1 5h
02	N/A	9 / Day 1 0 5h	265165 457	54840 377	4 835223	1	6 76	65	05104620000153	AA97220-01 05104620000153 02 N/A Serum-1 9 / Day 1 5h
02	N/A	10 / Day 1 0 75h	63992 137	44822 828	1 427668	1	2 00	68	05104620000122	AA97220-01 05104620000122 02 N/A Serum-1 10 / Day 1 75h
02	N/A	10 / Day 1 0 75h	71342 876	60301 021	1 183112	1	1 66	69	05104620000138	AA97220-01 05104620000138 02 N/A Serum-1 10 / Day 1 75h
02	N/A	10 / Day 1 0 75h	184918 416	53595	3 450292	1	4 82	67	05104620000154	AA97220-01 05104620000154 02 N/A Serum-1 10 / Day 1 75h
02	N/A	11 / Day 1 1h	76589 091	49549 26	1 545716	1	2 16	70	05104620000123	AA97220-01 05104620000123 02 N/A Serum-1 11 / Day 1 1h
02	N/A	11 / Day 1 1h	62188 344	56016 546	1 110178	1	1 55	72	05104620000139	AA97220-01 05104620000139 02 N/A Serum-1 11 / Day 1 1h
02	N/A	11 / Day 1 1h	179344 339	58059 287	3 088986	1	4 32	71	05104620000155	AA97220-01 05104620000155 02 N/A Serum-1 11 / Day 1 1h
02	N/A	12 / Day 1 1 25h	77119 233	52290 053	1 474836	1	2 06	76	05104620000124	AA97220-01 05104620000124 02 N/A Serum-1 12 / Day 1 1 25h
02	N/A	12 / Day 1 1 25h	68594 089	54610 46	1 256061	1	1 76	73	05104620000140	AA97220-01 05104620000140 02 N/A Serum-1 12 / Day 1 1 25h
02	N/A	12 / Day 1 1 25h	141874 698	58482 96	2 425915	1	3 39	75	05104620000156	AA97220-01 05104620000156 02 N/A Serum-1 12 / Day 1 1 25h
02	N/A	13 / Day 1 1 5h	64912 41	52981 332	1 225194	1	1 72	77	05104620000125	AA97220-01 05104620000125 02 N/A Serum-1 13 / Day 1 1 5h
02	N/A	13 / Day 1 1 5h	44031 083	49362 688	0 891991	1	1 25	78	05104620000141	AA97220-01 05104620000141 02 N/A Serum-1 13 / Day 1 1 5h
02	N/A	13 / Day 1 1 5h	119580 727	49648 313	2 408556	1	3 37	79	05104620000157	AA97220-01 05104620000157 02 N/A Serum-1 13 / Day 1 1 5h
02	N/A	14 / Day 1 2h	46617 217	49143 793	0 948588	1	1 33	82	05104620000126	AA97220-01 05104620000126 02 N/A Serum-1 14 / Day 1 2h
02	N/A	14 / Day 1 2h	36002 18	51283 568	0 702022	1	0 984	80	05104620000142	AA97220-01 05104620000142 02 N/A Serum-1 14 / Day 1 2h
02	N/A	14 / Day 1 2h	97178 471	50938 237	1 907771	1	2 67	81	05104620000158	AA97220-01 05104620000158 02 N/A Serum-1 14 / Day 1 2h
02	N/A	15 / Day 1 2 5h	55262 875	58593 898	0 943151	1	1 32	84	05104620000127	AA97220-01 05104620000127 02 N/A Serum-1 15 / Day 1 2 5h
02	N/A	15 / Day 1 2 5h	27438 92	49931 121	0 549535	1	0 772	83	05104620000143	AA97220-01 05104620000143 02 N/A Serum-1 15 / Day 1 2 5h
02	N/A	15 / Day 1 2 5h	90497 546	53652 557	1 686733	1	2 36	85	05104620000159	AA97220-01 05104620000159 02 N/A Serum-1 15 / Day 1 2 5h
02	N/A	16 / Day 1 3h	30994 917	46137 201	0 671799	1	0 942	87	05104620000128	AA97220-01 05104620000128 02 N/A Serum-1 16 / Day 1 3h
02	N/A	16 / Day 1 3h	26848 36	49157 95	0 546165	1	0 767	88	05104620000144	AA97220-01 05104620000144 02 N/A Serum-1 16 / Day 1 3h
02	N/A	16 / Day 1 3h	70127 747	51783 255	1 354255	1	1 90	86	05104620000160	AA97220-01 05104620000160 02 N/A Serum-1 16 / Day 1 3h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0.500 (Lowest Standard)

AAR - Concentration Found is Greater than 50.0 (Highest Standard)

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 3
 Serum, Concentration of Nicotine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		0	166417 116	0 000000	-0 0412		-0 0412	0 0
9	0 00		0	162398 162	0 000000	-0 0412			
10	0 500	4 00000	22208 272	165128 302	0 134491	0 477	-4 6		
11	1 00	1 00000	41868 55	142801 925	0 293193	1 09	9 0		
12	2 00	0 250000	87644 818	159614 352	0 549104	2 07	3 5		
13	4 00	0 0625000	169878 23	168301 113	1 009371	3 85	-3 8		
14	8 00	0 0156250	324045 115	163701 708	1 979485	7 59	-5 1		
15	10 0	0 0100000	395992 368	150381 98	2 633243	10 1	1 0		
16	20 0	0 00250000	865034 793	167325 612	5 169769	19 9	-0 5		
17	40 0	0 000625000	1602300 59	152844 768	10 483189	40 3	0 8		
18	50 0	0 000400000	2123607 806	163970 205	12 951181	49 9	-0 2		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:

Slope = 0 259548055

Intercept = 0 0106852516

R-Squared = 0 9973

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)

AAR - Concentration Found is Greater than 50 0 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 3
Serum, Concentration of Nicotine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	2095833 446	165551 853	12 659680	1	48 7		48 4		2 3
2	0 00	2041755 908	160221 292	12 743349	1	49 1				
3	0 00	1979109 263	162254 965	12 197527	1	47 0				
4	0 00	2177000 781	167167 784	13 022849	1	50 1				
5	0 00	1959239 437	154473 335	12 683350	1	48 8				
89	0 00	2170679 552	176157 243	12 322397	1	47 4				
90	0 00	2241468 666	180941 084	12 387837	1	47 7				
30	1 50	65882 377	151415 486	0 435110	1	1 64	9 3	1 55	3 3	8 6
63	1 50	57130 801	147193 358	0 388134	1	1 45	-3 3			
41	8 00	264353 842	139552 965	1 894290	1	7 26	-9 3	7 42	-7 3	3 0
74	8 00	310337 166	157021 465	1 976400	1	7 57	-5 4			
52	37 5	1113272 139	121388 973	9 171114	1	35 3	-5 9	36 0	-4 0	2 6
87	37 5	1625923 554	170901 281	9 513817	1	36 6	-2 4			

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)
AAR - Concentration Found is Greater than 50 0 (Highest Standard)

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 3
Serum, Concentration of Nicotine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
02	N/A	1 / Day 1 - 0 0333h	25822 836	179782 832	0 143633	1	0 512	20	05104620000081	AA97220-01 05104620000081 02 N/A Serum-1 1 / Day 1 - 0333h
02	N/A	1 / Day 1 - 0 0333h	24355 383	161117 683	0 151165	1	0 541	21	05104620000097	AA97220-01 05104620000097 02 N/A Serum-1 1 / Day 1 - 0333h
02	N/A	2 / Day 1 0h	26508 113	176877 673	0 149867	1	0 536	22	05104620000082	AA97220-01 05104620000082 02 N/A Serum-1 2 / Day 1 0h
02	N/A	2 / Day 1 0h	23195 725	162401 746	0 142829	1	0 509	23	05104620000098	AA97220-01 05104620000098 02 N/A Serum-1 2 / Day 1 0h
02	N/A	3 / Day 1 0 05h	21485 247	143154 171	0 150085	1	0 537	25	05104620000083	AA97220-01 05104620000083 02 N/A Serum-1 3 / Day 1 05h
02	N/A	3 / Day 1 0 05h	45677 483	160207 242	0 285115	1	1 06	24	05104620000099	AA97220-01 05104620000099 02 N/A Serum-1 3 / Day 1 05h
02	N/A	4 / Day 1 0 0833h	21264 547	146160 538	0 145488	1	0 519	27	05104620000084	AA97220-01 05104620000084 02 N/A Serum-1 4 / Day 1 0833h
02	N/A	4 / Day 1 0 0833h	64978 192	157942 898	0 411403	1	1 54	26	05104620000100	AA97220-01 05104620000100 02 N/A Serum-1 4 / Day 1 0833h
02	N/A	5 / Day 1 0 125h	31182 955	157134 986	0 198447	1	0 723	29	05104620000085	AA97220-01 05104620000085 02 N/A Serum-1 5 / Day 1 125h
02	N/A	5 / Day 1 0 125h	79443 883	157740 807	0 503636	1	1 90	28	05104620000101	AA97220-01 05104620000101 02 N/A Serum-1 5 / Day 1 125h
02	N/A	6 / Day 1 0 1667h	39518 847	147032 507	0 268776	1	0 994	31	05104620000086	AA97220-01 05104620000086 02 N/A Serum-1 6 / Day 1 1667h
02	N/A	6 / Day 1 0 1667h	97052 292	164230 812	0 590951	1	2 24	32	05104620000102	AA97220-01 05104620000102 02 N/A Serum-1 6 / Day 1 1667h
02	N/A	7 / Day 1 0 25h	48453 445	156301 62	0 310000	1	1 15	34	05104620000087	AA97220-01 05104620000087 02 N/A Serum-1 7 / Day 1 25h
02	N/A	7 / Day 1 0 25h	129826 113	148256 408	0 875686	1	3 33	33	05104620000103	AA97220-01 05104620000103 02 N/A Serum-1 7 / Day 1 25h
02	N/A	8 / Day 1 0 333h	65072 47	164895 873	0 394628	1	1 48	36	05104620000088	AA97220-01 05104620000088 02 N/A Serum-1 8 / Day 1 333h
02	N/A	8 / Day 1 0 333h	217352 597	152801 408	1 422452	1	5 44	35	05104620000104	AA97220-01 05104620000104 02 N/A Serum-1 8 / Day 1 333h
02	N/A	9 / Day 1 0 5h	56808 787	150296 343	0 377979	1	1 42	38	05104620000089	AA97220-01 05104620000089 02 N/A Serum-1 9 / Day 1 5h
02	N/A	9 / Day 1 0 5h	294742 862	143130 365	2 059262	1	7 89	37	05104620000105	AA97220-01 05104620000105 02 N/A Serum-1 9 / Day 1 5h
02	N/A	10 / Day 1 0 75h	59177 851	153511 052	0 385496	1	1 44	40	05104620000090	AA97220-01 05104620000090 02 N/A Serum-1 10 / Day 1 75h
02	N/A	10 / Day 1 0 75h	311872 371	134787 03	2 313816	1	8 87	39	05104620000106	AA97220-01 05104620000106 02 N/A Serum-1 10 / Day 1 75h
02	N/A	11 / Day 1 1h	62336 458	150339 942	0 414637	1	1 56	42	05104620000091	AA97220-01 05104620000091 02 N/A Serum-1 11 / Day 1 1h
02	N/A	11 / Day 1 1h	272162 362	149716 379	1 817853	1	6 96	43	05104620000107	AA97220-01 05104620000107 02 N/A Serum-1 11 / Day 1 1h
02	N/A	12 / Day 1 1 25h	59839 595	138412 128	0 432329	1	1 62	44	05104620000092	AA97220-01 05104620000092 02 N/A Serum-1 12 / Day 1 1 25h
02	N/A	12 / Day 1 1 25h	210886 87	141558 645	1 489749	1	5 70	45	05104620000108	AA97220-01 05104620000108 02 N/A Serum-1 12 / Day 1 1 25h
02	N/A	13 / Day 1 1 5h	55453 715	141976 98	0 390582	1	1 46	47	05104620000093	AA97220-01 05104620000093 02 N/A Serum-1 13 / Day 1 1 5h
02	N/A	13 / Day 1 1 5h	157647 009	130951 113	1 203862	1	4 60	46	05104620000109	AA97220-01 05104620000109 02 N/A Serum-1 13 / Day 1 1 5h
02	N/A	14 / Day 1 2h	47766 037	133345 977	0 358211	1	1 34	49	05104620000094	AA97220-01 05104620000094 02 N/A Serum-1 14 / Day 1 2h
02	N/A	14 / Day 1 2h	111168 607	119882 959	0 927310	1	3 53	48	05104620000110	AA97220-01 05104620000110 02 N/A Serum-1 14 / Day 1 2h
02	N/A	15 / Day 1 2 5h	39479 343	137056 563	0 288051	1	1 07	50	05104620000095	AA97220-01 05104620000095 02 N/A Serum-1 15 / Day 1 2 5h
02	N/A	15 / Day 1 2 5h	88569 827	128657 78	0 688414	1	2 61	51	05104620000111	AA97220-01 05104620000111 02 N/A Serum-1 15 / Day 1 2 5h
02	N/A	16 / Day 1 3h	37298 54	149120 962	0 250123	1	0 923	54	05104620000096	AA97220-01 05104620000096 02 N/A Serum-1 16 / Day 1 3h
02	N/A	16 / Day 1 3h	92441 525	142714 543	0 647737	1	2 45	53	05104620000112	AA97220-01 05104620000112 02 N/A Serum-1 16 / Day 1 3h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
03	N/A	1 / Day 1 - 0 0333h	131837 397	158432 513	0 832136	1	3 16	55	05104620000209	AA97220-01 05104620000209 03 N/A Serum-1 1 / Day 1 - 0333h
03	N/A	1 / Day 1 - 0 0333h	128529 977	160293 367	0 801842	1	3 05	56	05104620000225	AA97220-01 05104620000225 03 N/A Serum-1 1 / Day 1 - 0333h
03	N/A	2 / Day 1 0h	115533 153	154714 228	0 746752	1	2 84	57	05104620000210	AA97220-01 05104620000210 03 N/A Serum-1 2 / Day 1 0h
03	N/A	2 / Day 1 0h	236812 072	149763 222	1 581243	1	6 05	58	05104620000226	AA97220-01 05104620000226 03 N/A Serum-1 2 / Day 1 0h
03	N/A	3 / Day 1 0 05h	131887 48	148763 912	0 886556	1	3 37	60	05104620000211	AA97220-01 05104620000211 03 N/A Serum-1 3 / Day 1 05h
03	N/A	3 / Day 1 0 05h	268718 48	144067 862	1 865222	1	7 15	59	05104620000227	AA97220-01 05104620000227 03 N/A Serum-1 3 / Day 1 05h
03	N/A	4 / Day 1 0 0833h	127926 732	143143 67	0 893695	1	3 40	62	05104620000212	AA97220-01 05104620000212 03 N/A Serum-1 4 / Day 1 0833h
03	N/A	4 / Day 1 0 0833h	525857 995	153342 098	3 429313	1	13 2	61	05104620000228	AA97220-01 05104620000228 03 N/A Serum-1 4 / Day 1 0833h
03	N/A	5 / Day 1 0 125h	132087 627	138032 407	0 956932	1	3 65	64	05104620000213	AA97220-01 05104620000213 03 N/A Serum-1 5 / Day 1 125h
03	N/A	6 / Day 1 0 1667h	135296 822	139315 06	0 971157	1	3 70	65	05104620000214	AA97220-01 05104620000214 03 N/A Serum-1 6 / Day 1 1667h
03	N/A	7 / Day 1 0 25h	152914 773	149476 417	1 023003	1	3 90	66	05104620000215	AA97220-01 05104620000215 03 N/A Serum-1 7 / Day 1 25h
03	N/A	7 / Day 1 0 25h	591996 325	140127 236	4 224706	1	16 2	67	05104620000231	AA97220-01 05104620000231 03 N/A Serum-1 7 / Day 1 25h
03	N/A	8 / Day 1 0 333h	184112 484	149166 249	1 234277	1	4 71	69	05104620000216	AA97220-01 05104620000216 03 N/A Serum-1 8 / Day 1 333h
03	N/A	8 / Day 1 0 333h	612333 621	148611 9	4 120354	1	15 8	68	05104620000232	AA97220-01 05104620000232 03 N/A Serum-1 8 / Day 1 333h
03	N/A	9 / Day 1 0 5h	204597 424	144400 45	1 416875	1	5 42	71	05104620000217	AA97220-01 05104620000217 03 N/A Serum-1 9 / Day 1 5h
03	N/A	9 / Day 1 0 5h	521448 435	150906 797	3 455434	1	13 3	70	05104620000233	AA97220-01 05104620000233 03 N/A Serum-1 9 / Day 1 5h
03	N/A	10 / Day 1 0 75h	249352 076	147774 143	1 687386	1	6 46	73	05104620000218	AA97220-01 05104620000218 03 N/A Serum-1 10 / Day 1 75h
03	N/A	10 / Day 1 0 75h	519193 355	156062 722	3 326825	1	12 8	72	05104620000234	AA97220-01 05104620000234 03 N/A Serum-1 10 / Day 1 75h
03	N/A	11 / Day 1 1h	216328 912	155084 559	1 394909	1	5 33	76	05104620000219	AA97220-01 05104620000219 03 N/A Serum-1 11 / Day 1 1h
03	N/A	11 / Day 1 1h	456987 5	153748 168	2 972312	1	11 4	75	05104620000235	AA97220-01 05104620000235 03 N/A Serum-1 11 / Day 1 1h
03	N/A	12 / Day 1 1 25h	207399 608	153610 798	1 350163	1	5 16	77	05104620000220	AA97220-01 05104620000220 03 N/A Serum-1 12 / Day 1 1 25h
03	N/A	12 / Day 1 1 25h	440418 828	157574 667	2 794985	1	10 7	78	05104620000236	AA97220-01 05104620000236 03 N/A Serum-1 12 / Day 1 1 25h
03	N/A	13 / Day 1 1 5h	216322 303	164061 255	1 318546	1	5 04	80	05104620000221	AA97220-01 05104620000221 03 N/A Serum-1 13 / Day 1 1 5h
03	N/A	13 / Day 1 1 5h	402571 846	167913 967	2 397489	1	9 20	79	05104620000237	AA97220-01 05104620000237 03 N/A Serum-1 13 / Day 1 1 5h
03	N/A	14 / Day 1 2h	236454 477	175637 105	1 346267	1	5 15	82	05104620000222	AA97220-01 05104620000222 03 N/A Serum-1 14 / Day 1 2h
03	N/A	14 / Day 1 2h	421168 981	147318 19	2 858907	1	11 0	81	05104620000238	AA97220-01 05104620000238 03 N/A Serum-1 14 / Day 1 2h
03	N/A	15 / Day 1 2 5h	216686 055	191928 38	1 128994	1	4 31	84	05104620000223	AA97220-01 05104620000223 03 N/A Serum-1 15 / Day 1 2 5h
03	N/A	15 / Day 1 2 5h	373256 172	174255 077	2 142010	1	8 21	83	05104620000239	AA97220-01 05104620000239 03 N/A Serum-1 15 / Day 1 2 5h
03	N/A	16 / Day 1 3h	172410 892	156464 584	1 101916	1	4 20	86	05104620000224	AA97220-01 05104620000224 03 N/A Serum-1 16 / Day 1 3h
03	N/A	16 / Day 1 3h	347934 22	190388 835	1 827493	1	7 00	85	05104620000240	AA97220-01 05104620000240 03 N/A Serum-1 16 / Day 1 3h

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)
AAR - Concentration Found is Greater than 50 0 (Highest Standard)

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 4
 Serum, Concentration of Nicotine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		0	137988 284	0 000000	-0 0478		-0 0478	0 0
9	0 00		0	140415 165	0 000000	-0 0478			
10	0 500	4 00000	22422 725	158454 385	0 141509	0 495	-1 0		
11	1 00	1 00000	47066 593	169883 613	0 277052	1 01	1 0		
12	2 00	0 250000	84255 918	151477 358	0 556228	2 08	4 0		
13	4 00	0 0625000	174349 359	173241 745	1 006393	3 81	-4 8		
14	8 00	0 0156250	308767 281	145674 15	2 119575	8 08	1 0		
15	10 0	0 0100000	474885 023	189872 212	2 501077	9 54	-4 6		
16	20 0	0 00250000	915374 167	172218 722	5 315184	20 3	1 5		
17	40 0	0 000625000	1511402 804	140540 014	10 754253	41 2	3 0		
18	50 0	0 000400000	1778143 259	137243 141	12 956154	49 6	-0 8		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:

Slope = 0 260866894

Intercept = 0 0124750339

R-Squared = 0 9987

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)

AAR - Concentration Found is Greater than 50 0 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 4
Serum, Concentration of Nicotine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	1801476 722	144609 273	12 457546	1	47 7		47 8		2 0
2	0 00	2100231 5	162126 186	12 954302	1	49 6				
3	0 00	2035994 364	162865 124	12 501107	1	47 9				
4	0 00	1697202 951	137205 773	12 369763	1	47 4				
5	0 00	1470322 852	118871 958	12 368963	1	47 4				
91	0 00	1854817 256	152478 4	12 164459	1	46 6				
92	0 00	1990730 457	157904 857	12 607152	1	48 3				
30	1 50	60444 052	168320 42	0 359101	1	1 33	-11 3	1 39	-7 3	5 6
63	1 50	72856 259	188222 438	0 387075	1	1 44	-4 0			
41	8 00	306190 392	155621 172	1 967537	1	7 49	-6 4	7 52	-6 0	0 6
74	8 00	395029 53	199408 151	1 981010	1	7 55	-5 6			
52	37 5	1330019 457	134734 323	9 871423	1	37 8	0 8	37 0	-1 3	3 1
89	37 5	1369524 869	144929 652	9 449584	1	36 2	-3 5			

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)
AAR - Concentration Found is Greater than 50 0 (Highest Standard)

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 4
Serum, Concentration of Nicotine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
03	N/A	1 / Day 1 - 0 0333h	83401 885	149565 09	0 557629	1	2 09	20	05104620000161	AA97220-01 05104620000161 03 N/A Serum-1 1 / Day 1 - 0333h
03	N/A	1 / Day 1 - 0 0333h	87034 739	144785 968	0 601127	1	2 26	21	05104620000177	AA97220-01 05104620000177 03 N/A Serum-1 1 / Day 1 - 0333h
03	N/A	1 / Day 1 - 0 0333h	90812 335	137470 014	0 660597	1	2 48	22	05104620000193	AA97220-01 05104620000193 03 N/A Serum-1 1 / Day 1 - 0333h
03	N/A	2 / Day 1 0h	80491 088	135693 637	0 593182	1	2 23	23	05104620000162	AA97220-01 05104620000162 03 N/A Serum-1 2 / Day 1 0h
03	N/A	2 / Day 1 0h	97376 448	143167 962	0 680155	1	2 56	24	05104620000178	AA97220-01 05104620000178 03 N/A Serum-1 2 / Day 1 0h
03	N/A	2 / Day 1 0h	79547 623	141171 97	0 563480	1	2 11	25	05104620000194	AA97220-01 05104620000194 03 N/A Serum-1 2 / Day 1 0h
03	N/A	3 / Day 1 0 05h	85710 635	152766 615	0 561056	1	2 10	26	05104620000163	AA97220-01 05104620000163 03 N/A Serum-1 3 / Day 1 05h
03	N/A	3 / Day 1 0 05h	85295 62	146315 168	0 582958	1	2 19	28	05104620000179	AA97220-01 05104620000179 03 N/A Serum-1 3 / Day 1 05h
03	N/A	3 / Day 1 0 05h	98833 214	147869 62	0 668381	1	2 51	27	05104620000195	AA97220-01 05104620000195 03 N/A Serum-1 3 / Day 1 05h
03	N/A	4 / Day 1 0 0833h	77967 352	146045 108	0 533858	1	2 00	32	05104620000164	AA97220-01 05104620000164 03 N/A Serum-1 4 / Day 1 0833h
03	N/A	4 / Day 1 0 0833h	90604 908	142001 367	0 638057	1	2 40	31	05104620000180	AA97220-01 05104620000180 03 N/A Serum-1 4 / Day 1 0833h
03	N/A	4 / Day 1 0 0833h	118892 936	147697 242	0 804977	1	3 04	29	05104620000196	AA97220-01 05104620000196 03 N/A Serum-1 4 / Day 1 0833h
03	N/A	5 / Day 1 0 125h	76641 112	127030 769	0 603327	1	2 26	35	05104620000165	AA97220-01 05104620000165 03 N/A Serum-1 5 / Day 1 125h
03	N/A	5 / Day 1 0 125h	104294 576	129752 277	0 803798	1	3 03	34	05104620000181	AA97220-01 05104620000181 03 N/A Serum-1 5 / Day 1 125h
03	N/A	5 / Day 1 0 125h	85030 617	135179 684	0 629019	1	2 36	33	05104620000197	AA97220-01 05104620000197 03 N/A Serum-1 5 / Day 1 125h
03	N/A	6 / Day 1 0 1667h	94205 753	130154 568	0 723799	1	2 73	36	05104620000166	AA97220-01 05104620000166 03 N/A Serum-1 6 / Day 1 1667h
03	N/A	6 / Day 1 0 1667h	135931 941	160367 23	0 847629	1	3 20	38	05104620000182	AA97220-01 05104620000182 03 N/A Serum-1 6 / Day 1 1667h
03	N/A	6 / Day 1 0 1667h	92255 003	129201 917	0 714037	1	2 69	37	05104620000198	AA97220-01 05104620000198 03 N/A Serum-1 6 / Day 1 1667h
03	N/A	7 / Day 1 0 25h	114661 449	135084 963	0 848810	1	3 21	39	05104620000167	AA97220-01 05104620000167 03 N/A Serum-1 7 / Day 1 25h
03	N/A	7 / Day 1 0 25h	136666 454	139312 243	0 981008	1	3 71	40	05104620000183	AA97220-01 05104620000183 03 N/A Serum-1 7 / Day 1 25h
03	N/A	7 / Day 1 0 25h	121894 134	143122 858	0 851675	1	3 22	42	05104620000199	AA97220-01 05104620000199 03 N/A Serum-1 7 / Day 1 25h
03	N/A	8 / Day 1 0 333h	127284 587	140377 838	0 906729	1	3 43	44	05104620000168	AA97220-01 05104620000168 03 N/A Serum-1 8 / Day 1 333h
03	N/A	8 / Day 1 0 333h	144578 492	139665 663	1 035176	1	3 92	43	05104620000184	AA97220-01 05104620000184 03 N/A Serum-1 8 / Day 1 333h
03	N/A	8 / Day 1 0 333h	157378 339	135240 51	1 163692	1	4 41	45	05104620000200	AA97220-01 05104620000200 03 N/A Serum-1 8 / Day 1 333h
03	N/A	9 / Day 1 0 5h	107440 675	100483 19	1 069240	1	4 05	48	05104620000169	AA97220-01 05104620000169 03 N/A Serum-1 9 / Day 1 5h
03	N/A	9 / Day 1 0 5h	164385 07	144055 962	1 141120	1	4 33	47	05104620000185	AA97220-01 05104620000185 03 N/A Serum-1 9 / Day 1 5h
03	N/A	9 / Day 1 0 5h	206773 119	163899 631	1 261584	1	4 79	46	05104620000201	AA97220-01 05104620000201 03 N/A Serum-1 9 / Day 1 5h
03	N/A	10 / Day 1 0 75h	160486 285	147144 677	1 090670	1	4 13	50	05104620000170	AA97220-01 05104620000170 03 N/A Serum-1 10 / Day 1 75h
03	N/A	10 / Day 1 0 75h	177692 354	142874 677	1 243694	1	4 72	51	05104620000186	AA97220-01 05104620000186 03 N/A Serum-1 10 / Day 1 75h
03	N/A	10 / Day 1 0 75h	201275 529	139582 871	1 441979	1	5 48	49	05104620000202	AA97220-01 05104620000202 03 N/A Serum-1 10 / Day 1 75h
03	N/A	11 / Day 1 1h	174766 067	179086 127	0 975877	1	3 69	54	05104620000171	AA97220-01 05104620000171 03 N/A Serum-1 11 / Day 1 1h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
03	N/A	11 / Day 1 1h	177835 696	170086 448	1 045561	1	3 96	55	05104620000187	AA97220-01 05104620000187 03 N/A Serum-1 11 / Day 1 1h
03	N/A	11 / Day 1 1h	223824 189	164896 268	1 357364	1	5 16	53	05104620000203	AA97220-01 05104620000203 03 N/A Serum-1 11 / Day 1 1h
03	N/A	12 / Day 1 1 25h	157556 74	163213 655	0 965340	1	3 65	57	05104620000172	AA97220-01 05104620000172 03 N/A Serum-1 12 / Day 1 1 25h
03	N/A	12 / Day 1 1 25h	195393 021	175441 63	1 113721	1	4 22	58	05104620000188	AA97220-01 05104620000188 03 N/A Serum-1 12 / Day 1 1 25h
03	N/A	12 / Day 1 1 25h	219564 505	158738 603	1 383183	1	5 25	56	05104620000204	AA97220-01 05104620000204 03 N/A Serum-1 12 / Day 1 1 25h
03	N/A	13 / Day 1 1 5h	177208 972	178898 102	0 990558	1	3 75	61	05104620000173	AA97220-01 05104620000173 03 N/A Serum-1 13 / Day 1 1 5h
03	N/A	13 / Day 1 1 5h	177043 745	165004 752	1 072961	1	4 07	59	05104620000189	AA97220-01 05104620000189 03 N/A Serum-1 13 / Day 1 1 5h
03	N/A	13 / Day 1 1 5h	234223 673	180217 38	1 299673	1	4 93	60	05104620000205	AA97220-01 05104620000205 03 N/A Serum-1 13 / Day 1 1 5h
03	N/A	14 / Day 1 2h	202335 215	193816 81	1 043951	1	3 95	62	05104620000174	AA97220-01 05104620000174 03 N/A Serum-1 14 / Day 1 2h
03	N/A	14 / Day 1 2h	185925 232	186471 648	0 997070	1	3 77	65	05104620000190	AA97220-01 05104620000190 03 N/A Serum-1 14 / Day 1 2h
03	N/A	14 / Day 1 2h	214195 001	171922 652	1 245880	1	4 73	64	05104620000206	AA97220-01 05104620000206 03 N/A Serum-1 14 / Day 1 2h
03	N/A	15 / Day 1 2 5h	153296 538	180958 387	0 847137	1	3 20	66	05104620000175	AA97220-01 05104620000175 03 N/A Serum-1 15 / Day 1 2 5h
03	N/A	15 / Day 1 2 5h	171811 542	189159 977	0 908287	1	3 43	67	05104620000191	AA97220-01 05104620000191 03 N/A Serum-1 15 / Day 1 2 5h
03	N/A	15 / Day 1 2 5h	193984 629	182006 487	1 065812	1	4 04	68	05104620000207	AA97220-01 05104620000207 03 N/A Serum-1 15 / Day 1 2 5h
03	N/A	16 / Day 1 3h	153595 924	189822 62	0 809155	1	3 05	69	05104620000176	AA97220-01 05104620000176 03 N/A Serum-1 16 / Day 1 3h
03	N/A	16 / Day 1 3h	129900 597	169852 5	0 764785	1	2 88	71	05104620000192	AA97220-01 05104620000192 03 N/A Serum-1 16 / Day 1 3h
03	N/A	16 / Day 1 3h	164927 23	175456 377	0 939990	1	3 56	70	05104620000208	AA97220-01 05104620000208 03 N/A Serum-1 16 / Day 1 3h
04	N/A	1 / Day 1 - 0 0333h	28119 563	147872 077	0 190161	1	0 681	72	05104620000305	AA97220-01 05104620000305 04 N/A Serum-1 1 / Day 1 - 0333h
04	N/A	2 / Day 1 0h	29590 788	174676 903	0 169403	1	0 602	73	05104620000306	AA97220-01 05104620000306 04 N/A Serum-1 2 / Day 1 0h
04	N/A	3 / Day 1 0 05h	1391883 643	176450 087	7 888257	1	30 2	75	05104620000307	AA97220-01 05104620000307 04 N/A Serum-1 3 / Day 1 05h
04	N/A	4 / Day 1 0 0833h	1850753 862	187946 683	9 847228	1	37 7	76	05104620000308	AA97220-01 05104620000308 04 N/A Serum-1 4 / Day 1 0833h
04	N/A	5 / Day 1 0 125h	1030277 96	180836 299	5 697296	1	21 8	77	05104620000309	AA97220-01 05104620000309 04 N/A Serum-1 5 / Day 1 125h
04	N/A	6 / Day 1 0 1667h	855678 208	177742 397	4 814148	1	18 4	78	05104620000310	AA97220-01 05104620000310 04 N/A Serum-1 6 / Day 1 1667h
04	N/A	7 / Day 1 0 25h	548514 954	150142 346	3 653299	1	14 0	79	05104620000311	AA97220-01 05104620000311 04 N/A Serum-1 7 / Day 1 25h
04	N/A	8 / Day 1 0 333h	466185 973	168329 885	2 769478	1	10 6	80	05104620000312	AA97220-01 05104620000312 04 N/A Serum-1 8 / Day 1 333h
04	N/A	9 / Day 1 0 5h	266175 341	131526 76	2 023735	1	7 71	81	05104620000313	AA97220-01 05104620000313 04 N/A Serum-1 9 / Day 1 5h
04	N/A	10 / Day 1 0 75h	104186 577	65244 582	*1 596862	1	*6 07	82	05104620000314	AA97220-01 05104620000314 04 N/A Serum-1 10 / Day 1 75h
04	N/A	11 / Day 1 1h	184770 038	121935 9	1 515305	1	5 76	83	05104620000315	AA97220-01 05104620000315 04 N/A Serum-1 11 / Day 1 1h
04	N/A	12 / Day 1 1 25h	149233 815	139031 137	1 073384	1	4 07	84	05104620000316	AA97220-01 05104620000316 04 N/A Serum-1 12 / Day 1 1 25h
04	N/A	13 / Day 1 1 5h	116020 992	120682 172	0 961376	1	3 64	85	05104620000317	AA97220-01 05104620000317 04 N/A Serum-1 13 / Day 1 1 5h
04	N/A	14 / Day 1 2h	62393 516	93793 052	0 665225	1	2 50	86	05104620000318	AA97220-01 05104620000318 04 N/A Serum-1 14 / Day 1 2h
04	N/A	15 / Day 1 2 5h	89752 073	131830 887	0 680812	1	2 56	87	05104620000319	AA97220-01 05104620000319 04 N/A Serum-1 15 / Day 1 2 5h
04	N/A	16 / Day 1 3h	87502 915	136808 538	0 639601	1	2 40	88	05104620000320	AA97220-01 05104620000320 04 N/A Serum-1 16 / Day 1 3h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0.500 (Lowest Standard)

AAR - Concentration Found is Greater than 50.0 (Highest Standard)

* - Sample Rejected

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 5
Serum, Concentration of Nicotine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		7693 284	64713 872	0 118882	0 115		0 0299	401 3
9	0 00		0	58383 862	0 000000	-0 0552			
10	0 500	4 00000	24151 157	62307 889	0 387610	0 501	0 2		
11	1 00	1 00000	41206 987	56661 593	0 727247	0 989	-1 1		
12	2 00	0 250000	82677 02	58027 598	1 424788	1 99	-0 5		
13	4 00	0 0625000	157953 051	54946 373	2 874677	4 07	1 8		
14	8 00	0 0156250	290752 803	50391 758	5 769848	8 23	2 9		
15	10 0	0 0100000	448817 273	63262 862	7 094483	10 1	1 0		
16	20 0	0 00250000	955939 701	69509 508	13 752647	19 7	-1 5		
17	40 0	0 000625000	1309116 052	47839 485	27 364761	39 2	-2 0		
18	50 0	0 000400000	1891025 081	54945 076	34 416643	49 4	-1 2		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:
Slope = 0 696412744
Intercept = 0 0384715211
R-Squared = 0 9996

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)
AAR - Concentration Found is Greater than 50 0 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 5
Serum, Concentration of Nicotine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	1660629 442	47121 325	35 241569	1	50 5		50 4		1 1
2	0 00	1595290 404	45367 834	35 163469	1	50 4				
3	0 00	1710182 316	48708 107	35 110835	1	50 4				
4	0 00	1623364 989	46805 552	34 683172	1	49 7				
5	0 00	1461100 929	42205 611	34 618642	1	49 7				
91	0 00	1874984 365	52743 585	35 549050	1	51 0				
92	0 00	1468339 172	41188 737	35 649046	1	51 1				
30	1 50	56456 379	56674 195	0 996157	1	1 38	-8 0	1 48	-1 3	9 1
63	1 50	62328 417	55164 73	1 129860	1	1 57	4 7			
41	8 00	356448 76	63378 8	5 624101	1	8 02	0 3	7 94	-0 8	1 5
74	8 00	327395 303	59461 43	5 506011	1	7 85	-1 9			
52	37 5	1574206 327	57925 387	27 176449	1	39 0	4 0	38 9	3 7	0 5
89	37 5	1605902 616	59478 783	26 999588	1	38 7	3 2			

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)
AAR - Concentration Found is Greater than 50 0 (Highest Standard)

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 5
Serum, Concentration of Nicotine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
04	N/A	1 / Day 1 -0 0333h	30787 232	59613 508	0 516447	1	0 686	21	05104620000241	AA97220-01 05104620000241 04 N/A Serum-1 1 / Day 1 - 0333h
04	N/A	1 / Day 1 -0 0333h	16284 133	63748 868	0 255442	1	BLQ<(0 500)	22	05104620000257	AA97220-01 05104620000257 04 N/A Serum-1 1 / Day 1 - 0333h
04	N/A	1 / Day 1 -0 0333h	44418 818	40944 563	1 084853	1	1 50	20	05104620000273	AA97220-01 05104620000273 04 N/A Serum-1 1 / Day 1 - 0333h
04	N/A	1 / Day 1 -0 0333h	51479 4	62826 638	0 819388	1	1 12	23	05104620000289	AA97220-01 05104620000289 04 N/A Serum-1 1 / Day 1 - 0333h
04	N/A	2 / Day 1 0h	27185 962	56279 583	0 483052	1	0 638	25	05104620000242	AA97220-01 05104620000242 04 N/A Serum-1 2 / Day 1 0h
04	N/A	2 / Day 1 0h	18145 695	61018 347	0 297381	1	BLQ<(0 500)	26	05104620000258	AA97220-01 05104620000258 04 N/A Serum-1 2 / Day 1 0h
04	N/A	2 / Day 1 0h	52938 73	50600 288	1 046214	1	1 45	27	05104620000274	AA97220-01 05104620000274 04 N/A Serum-1 2 / Day 1 0h
04	N/A	2 / Day 1 0h	36528 24	55147 165	0 662377	1	0 896	24	05104620000290	AA97220-01 05104620000290 04 N/A Serum-1 2 / Day 1 0h
04	N/A	3 / Day 1 0 05h	32633 369	56001 76	0 582720	1	0 782	32	05104620000243	AA97220-01 05104620000243 04 N/A Serum-1 3 / Day 1 05h
04	N/A	3 / Day 1 0 05h	42258 974	56735 645	0 744840	1	1 01	31	05104620000259	AA97220-01 05104620000259 04 N/A Serum-1 3 / Day 1 05h
04	N/A	3 / Day 1 0 05h	63640 693	54041 083	1 177635	1	1 64	29	05104620000275	AA97220-01 05104620000275 04 N/A Serum-1 3 / Day 1 05h
04	N/A	3 / Day 1 0 05h	59519 327	61492 341	0 967914	1	1 33	28	05104620000291	AA97220-01 05104620000291 04 N/A Serum-1 3 / Day 1 05h
04	N/A	4 / Day 1 0 0833h	72460 365	61403 34	1 180072	1	1 64	35	05104620000244	AA97220-01 05104620000244 04 N/A Serum-1 4 / Day 1 0833h
04	N/A	4 / Day 1 0 0833h	67961 901	61747 595	1 100640	1	1 53	33	05104620000260	AA97220-01 05104620000260 04 N/A Serum-1 4 / Day 1 0833h
04	N/A	4 / Day 1 0 0833h	92872 632	61546 723	1 508978	1	2 11	34	05104620000276	AA97220-01 05104620000276 04 N/A Serum-1 4 / Day 1 0833h
04	N/A	4 / Day 1 0 0833h	81123 17	54864 248	1 478616	1	2 07	36	05104620000292	AA97220-01 05104620000292 04 N/A Serum-1 4 / Day 1 0833h
04	N/A	5 / Day 1 0 125h	130903 182	55281 998	2 367917	1	3 34	40	05104620000245	AA97220-01 05104620000245 04 N/A Serum-1 5 / Day 1 125h
04	N/A	5 / Day 1 0 125h	123336 48	68339 008	1 804774	1	2 54	39	05104620000261	AA97220-01 05104620000261 04 N/A Serum-1 5 / Day 1 125h
04	N/A	5 / Day 1 0 125h	70064 52	39411 792	1 777755	1	2 50	38	05104620000277	AA97220-01 05104620000277 04 N/A Serum-1 5 / Day 1 125h
04	N/A	5 / Day 1 0 125h	163747 182	62386 946	2 624703	1	3 71	37	05104620000293	AA97220-01 05104620000293 04 N/A Serum-1 5 / Day 1 125h
04	N/A	6 / Day 1 0 1667h	152176 61	60622 032	2 510253	1	3 55	42	05104620000246	AA97220-01 05104620000246 04 N/A Serum-1 6 / Day 1 1667h
04	N/A	6 / Day 1 0 1667h	114969 78	61693 962	1 863550	1	2 62	44	05104620000262	AA97220-01 05104620000262 04 N/A Serum-1 6 / Day 1 1667h
04	N/A	6 / Day 1 0 1667h	96929 345	60236 537	1 609145	1	2 26	43	05104620000278	AA97220-01 05104620000278 04 N/A Serum-1 6 / Day 1 1667h
04	N/A	6 / Day 1 0 1667h	190942 618	63200 712	3 021210	1	4 28	45	05104620000294	AA97220-01 05104620000294 04 N/A Serum-1 6 / Day 1 1667h
04	N/A	7 / Day 1 0 25h	116665 097	65291 38	1 786838	1	2 51	46	05104620000247	AA97220-01 05104620000247 04 N/A Serum-1 7 / Day 1 25h
04	N/A	7 / Day 1 0 25h	203683 306	61374 262	3 318709	1	4 71	47	05104620000263	AA97220-01 05104620000263 04 N/A Serum-1 7 / Day 1 25h
04	N/A	7 / Day 1 0 25h	123065 675	61155 242	2 012349	1	2 83	49	05104620000279	AA97220-01 05104620000279 04 N/A Serum-1 7 / Day 1 25h
04	N/A	7 / Day 1 0 25h	189243 347	55543 456	3 407122	1	4 84	48	05104620000295	AA97220-01 05104620000295 04 N/A Serum-1 7 / Day 1 25h
04	N/A	8 / Day 1 0 333h	128321 755	53236 925	2 410390	1	3 41	51	05104620000248	AA97220-01 05104620000248 04 N/A Serum-1 8 / Day 1 333h
04	N/A	8 / Day 1 0 333h	185498 678	58773 748	3 156149	1	4 48	54	05104620000264	AA97220-01 05104620000264 04 N/A Serum-1 8 / Day 1 333h
04	N/A	8 / Day 1 0 333h	110449 711	51030 77	2 164375	1	3 05	53	05104620000280	AA97220-01 05104620000280 04 N/A Serum-1 8 / Day 1 333h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
04	N/A	8 / Day 1 0 333h	270144 759	59041 337	4 575519	1	6 51	50	05104620000296	AA97220-01 05104620000296 04 N/A Serum-1 8 / Day 1 333h
04	N/A	9 / Day 1 0 5h	98193 826	56896 908	1 725820	1	2 42	56	05104620000249	AA97220-01 05104620000249 04 N/A Serum-1 9 / Day 1 5h
04	N/A	9 / Day 1 0 5h	147536 644	55290 768	2 668378	1	3 78	55	05104620000265	AA97220-01 05104620000265 04 N/A Serum-1 9 / Day 1 5h
04	N/A	9 / Day 1 0 5h	104414 691	61140 487	1 707783	1	2 40	57	05104620000281	AA97220-01 05104620000281 04 N/A Serum-1 9 / Day 1 5h
04	N/A	9 / Day 1 0 5h	234037 531	46573 742	5 025096	1	7 16	58	05104620000297	AA97220-01 05104620000297 04 N/A Serum-1 9 / Day 1 5h
04	N/A	10 / Day 1 0 75h	107282 538	63408 596	1 691924	1	2 37	59	05104620000250	AA97220-01 05104620000250 04 N/A Serum-1 10 / Day 1 75h
04	N/A	10 / Day 1 0 75h	160903 275	63189 388	2 546365	1	3 60	60	05104620000266	AA97220-01 05104620000266 04 N/A Serum-1 10 / Day 1 75h
04	N/A	10 / Day 1 0 75h	82599 85	53868 516	1 533360	1	2 15	62	05104620000282	AA97220-01 05104620000282 04 N/A Serum-1 10 / Day 1 75h
04	N/A	10 / Day 1 0 75h	195131 183	57187 469	3 412132	1	4 84	61	05104620000298	AA97220-01 05104620000298 04 N/A Serum-1 10 / Day 1 75h
04	N/A	11 / Day 1 1h	71534 52	58051 405	1 232262	1	1 71	64	05104620000251	AA97220-01 05104620000251 04 N/A Serum-1 11 / Day 1 1h
04	N/A	11 / Day 1 1h	84061 094	48132 95	1 746436	1	2 45	67	05104620000267	AA97220-01 05104620000267 04 N/A Serum-1 11 / Day 1 1h
04	N/A	11 / Day 1 1h	75278 162	41695 189	1 805440	1	2 54	65	05104620000283	AA97220-01 05104620000283 04 N/A Serum-1 11 / Day 1 1h
04	N/A	11 / Day 1 1h	160732 61	52505 599	3 061247	1	4 34	66	05104620000299	AA97220-01 05104620000299 04 N/A Serum-1 11 / Day 1 1h
04	N/A	12 / Day 1 1 25h	50948 136	46451 037	1 096814	1	1 52	71	05104620000252	AA97220-01 05104620000252 04 N/A Serum-1 12 / Day 1 1 25h
04	N/A	12 / Day 1 1 25h	76014 913	51119 409	1 487007	1	2 08	69	05104620000268	AA97220-01 05104620000268 04 N/A Serum-1 12 / Day 1 1 25h
04	N/A	12 / Day 1 1 25h	100676 323	60482 572	1 664551	1	2 33	68	05104620000284	AA97220-01 05104620000284 04 N/A Serum-1 12 / Day 1 1 25h
04	N/A	12 / Day 1 1 25h	142306 275	54457 735	2 613151	1	3 70	70	05104620000300	AA97220-01 05104620000300 04 N/A Serum-1 12 / Day 1 1 25h
04	N/A	13 / Day 1 1 5h	36500 913	38612 297	0 945318	1	1 30	73	05104620000253	AA97220-01 05104620000253 04 N/A Serum-1 13 / Day 1 1 5h
04	N/A	13 / Day 1 1 5h	68022 404	55091 962	1 234707	1	1 72	72	05104620000269	AA97220-01 05104620000269 04 N/A Serum-1 13 / Day 1 1 5h
04	N/A	13 / Day 1 1 5h	74566 894	46389 746	1 607400	1	2 25	75	05104620000285	AA97220-01 05104620000285 04 N/A Serum-1 13 / Day 1 1 5h
04	N/A	13 / Day 1 1 5h	119208 717	51185 962	2 328934	1	3 29	76	05104620000301	AA97220-01 05104620000301 04 N/A Serum-1 13 / Day 1 1 5h
04	N/A	14 / Day 1 2h	36818 907	52198 623	0 705362	1	0 958	80	05104620000254	AA97220-01 05104620000254 04 N/A Serum-1 14 / Day 1 2h
04	N/A	14 / Day 1 2h	51092 85	53549 815	0 954118	1	1 31	79	05104620000270	AA97220-01 05104620000270 04 N/A Serum-1 14 / Day 1 2h
04	N/A	14 / Day 1 2h	69556 462	48112 58	1 445702	1	2 02	78	05104620000286	AA97220-01 05104620000286 04 N/A Serum-1 14 / Day 1 2h
04	N/A	14 / Day 1 2h	103198 481	54987 087	1 876777	1	2 64	77	05104620000302	AA97220-01 05104620000302 04 N/A Serum-1 14 / Day 1 2h
04	N/A	15 / Day 1 2 5h	46607 557	63828 178	0 730203	1	0 993	82	05104620000255	AA97220-01 05104620000255 04 N/A Serum-1 15 / Day 1 2 5h
04	N/A	15 / Day 1 2 5h	37960 463	50090 456	0 757838	1	1 03	84	05104620000271	AA97220-01 05104620000271 04 N/A Serum-1 15 / Day 1 2 5h
04	N/A	15 / Day 1 2 5h	66357 388	52907 797	1 254208	1	1 75	83	05104620000287	AA97220-01 05104620000287 04 N/A Serum-1 15 / Day 1 2 5h
04	N/A	15 / Day 1 2 5h	80730 607	51839 211	1 557327	1	2 18	81	05104620000303	AA97220-01 05104620000303 04 N/A Serum-1 15 / Day 1 2 5h
04	N/A	16 / Day 1 3h	32158 746	55418 295	0 580291	1	0 778	86	05104620000256	AA97220-01 05104620000256 04 N/A Serum-1 16 / Day 1 3h
04	N/A	16 / Day 1 3h	37701 218	57208 809	0 659011	1	0 891	88	05104620000272	AA97220-01 05104620000272 04 N/A Serum-1 16 / Day 1 3h
04	N/A	16 / Day 1 3h	60397 762	55273 343	1 092710	1	1 51	87	05104620000288	AA97220-01 05104620000288 04 N/A Serum-1 16 / Day 1 3h
04	N/A	16 / Day 1 3h	67442 318	47276 982	1 426536	1	1 99	85	05104620000304	AA97220-01 05104620000304 04 N/A Serum-1 16 / Day 1 3h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0.500 (Lowest Standard)

AAR - Concentration Found is Greater than 50.0 (Highest Standard)

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 6
Serum, Concentration of Nicotine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		0	47962 512	0 000000	0 0227		0 0227	0 0
9	0 00		0	59216 718	0 000000	0 0227			
10	0 500	4 00000	13990 895	42304 942	0 330715	0 484	-3 2		
11	1 00	1 00000	51084 328	69845 645	0 731389	1 04	4 0		
12	2 00	0 250000	90635 61	61302 112	1 478507	2 09	4 5		
13	4 00	0 0625000	171709 285	60552 051	2 835730	3 98	-0 5		
14	8 00	0 0156250	344774 744	62019 15	5 559166	7 79	-2 6		
15	10 0	0 0100000	348347 659	47991 745	7 258491	10 2	2 0		
16	20 0	0 00250000	644492 333	45138 881	14 277986	20 0	0 0		
17	40 0	0 000625000	1357819 338	46270 444	29 345284	41 0	2 5		
18	50 0	0 000400000	1474635 136	44027 417	33 493565	46 8	-6 4		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:
Slope = 0 716132054
Intercept = -0 0162250449
R-Squared = 0 9982

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)
AAR - Concentration Found is Greater than 50 0 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 6
Serum, Concentration of Nicotine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	1872208 818	53662 726	34 888440	1	48 7		48 9		1 9
2	0 00	1487346 521	40958 118	36 313839	1	50 7				
3	0 00	1613776 397	46868 828	34 431763	1	48 1				
4	0 00	2092557 619	60773 557	34 432041	1	48 1				
5	0 00	1951220 975	54863 577	35 564961	1	49 7				
91	0 00	1768675 58	50698 939	34 885850	1	48 7				
92	0 00	1876595 922	53906 445	34 812088	1	48 6				
30	1 50	63493 66	55132 195	1 151662	1	1 63	8 7	1 59	6 0	3 6
63	1 50	52141 593	47601 442	1 095378	1	1 55	3 3			
41	8 00	271143 303	48464 822	5 594641	1	7 83	-2 1	7 82	-2 3	0 2
74	8 00	295257 198	52958 047	5 575304	1	7 81	-2 4			
52	37 5	1091150 013	38687 22	28 204405	1	39 4	5 1	39 3	4 8	0 5
89	37 5	1317021 987	47069 245	27 980521	1	39 1	4 3			

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)
AAR - Concentration Found is Greater than 50 0 (Highest Standard)

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 6
Serum, Concentration of Nicotine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
05	N/A	1 / Day 1 - 0 0333h	44260 927	48154 488	0 919144	1	1 31	20	05104620000337	AA97220-01 05104620000337 05 N/A Serum-1 1 / Day 1 - 0333h
05	N/A	1 / Day 1 - 0 0333h	25832 96	43993 067	0 587205	1	0 843	23	05104620000353	AA97220-01 05104620000353 05 N/A Serum-1 1 / Day 1 - 0333h
05	N/A	1 / Day 1 - 0 0333h	78524 324	52393 303	1 498747	1	2 12	22	05104620000369	AA97220-01 05104620000369 05 N/A Serum-1 1 / Day 1 - 0333h
05	N/A	1 / Day 1 - 0 0333h	38457 743	45538 803	0 844505	1	1 20	21	05104620000385	AA97220-01 05104620000385 05 N/A Serum-1 1 / Day 1 - 0333h
05	N/A	2 / Day 1 0h	44487 772	49749 183	0 894241	1	1 27	27	05104620000338	AA97220-01 05104620000338 05 N/A Serum-1 2 / Day 1 0h
05	N/A	2 / Day 1 0h	25158 29	47108 916	0 534045	1	0 768	26	05104620000354	AA97220-01 05104620000354 05 N/A Serum-1 2 / Day 1 0h
05	N/A	2 / Day 1 0h	75990 869	49656 999	1 530315	1	2 16	24	05104620000370	AA97220-01 05104620000370 05 N/A Serum-1 2 / Day 1 0h
05	N/A	2 / Day 1 0h	32968 738	41605 044	0 792422	1	1 13	25	05104620000386	AA97220-01 05104620000386 05 N/A Serum-1 2 / Day 1 0h
05	N/A	3 / Day 1 0 05h	56605 893	45192 339	1 252555	1	1 77	28	05104620000339	AA97220-01 05104620000339 05 N/A Serum-1 3 / Day 1 05h
05	N/A	3 / Day 1 0 05h	28620 463	49201 944	0 581694	1	0 835	32	05104620000355	AA97220-01 05104620000355 05 N/A Serum-1 3 / Day 1 05h
05	N/A	3 / Day 1 0 05h	64780 67	46211 296	1 401836	1	1 98	29	05104620000371	AA97220-01 05104620000371 05 N/A Serum-1 3 / Day 1 05h
05	N/A	3 / Day 1 0 05h	370990 783	41532 791	8 932479	1	12 5	31	05104620000387	AA97220-01 05104620000387 05 N/A Serum-1 3 / Day 1 05h
05	N/A	4 / Day 1 0 0833h	56710 107	45368 004	1 250002	1	1 77	33	05104620000340	AA97220-01 05104620000340 05 N/A Serum-1 4 / Day 1 0833h
05	N/A	4 / Day 1 0 0833h	50533 496	52208 795	0 967912	1	1 37	35	05104620000356	AA97220-01 05104620000356 05 N/A Serum-1 4 / Day 1 0833h
05	N/A	4 / Day 1 0 0833h	92397 745	56856 658	1 625100	1	2 29	36	05104620000372	AA97220-01 05104620000372 05 N/A Serum-1 4 / Day 1 0833h
05	N/A	4 / Day 1 0 0833h	514975 906	46477 062	11 080216	1	15 5	34	05104620000388	AA97220-01 05104620000388 05 N/A Serum-1 4 / Day 1 0833h
05	N/A	5 / Day 1 0 125h	75006 19	51611 921	1 453273	1	2 05	38	05104620000341	AA97220-01 05104620000341 05 N/A Serum-1 5 / Day 1 125h
05	N/A	5 / Day 1 0 125h	52385 812	40101 14	1 306342	1	1 85	37	05104620000357	AA97220-01 05104620000357 05 N/A Serum-1 5 / Day 1 125h
05	N/A	5 / Day 1 0 125h	96383 393	43239 712	2 229048	1	3 14	39	05104620000373	AA97220-01 05104620000373 05 N/A Serum-1 5 / Day 1 125h
05	N/A	5 / Day 1 0 125h	591599 592	51786 237	11 423877	1	16 0	40	05104620000389	AA97220-01 05104620000389 05 N/A Serum-1 5 / Day 1 125h
05	N/A	6 / Day 1 0 1667h	64578 662	42699 633	1 512394	1	2 13	43	05104620000342	AA97220-01 05104620000342 05 N/A Serum-1 6 / Day 1 1667h
05	N/A	6 / Day 1 0 1667h	67533 712	45778 528	1 475227	1	2 08	42	05104620000358	AA97220-01 05104620000358 05 N/A Serum-1 6 / Day 1 1667h
05	N/A	6 / Day 1 0 1667h	117337 339	43438 072	2 701256	1	3 79	45	05104620000374	AA97220-01 05104620000374 05 N/A Serum-1 6 / Day 1 1667h
05	N/A	6 / Day 1 0 1667h	404789 16	46249 767	8 752242	1	12 2	44	05104620000390	AA97220-01 05104620000390 05 N/A Serum-1 6 / Day 1 1667h
05	N/A	7 / Day 1 0 25h	67532 289	43273 259	1 560601	1	2 20	48	05104620000343	AA97220-01 05104620000343 05 N/A Serum-1 7 / Day 1 25h
05	N/A	7 / Day 1 0 25h	60191 047	40511 422	1 485780	1	2 10	47	05104620000359	AA97220-01 05104620000359 05 N/A Serum-1 7 / Day 1 25h
05	N/A	7 / Day 1 0 25h	139063 095	54424 063	2 555177	1	3 59	49	05104620000375	AA97220-01 05104620000375 05 N/A Serum-1 7 / Day 1 25h
05	N/A	7 / Day 1 0 25h	312619 25	41341 585	7 561859	1	10 6	46	05104620000391	AA97220-01 05104620000391 05 N/A Serum-1 7 / Day 1 25h
05	N/A	8 / Day 1 0 333h	71974 717	41756 32	1 723684	1	2 43	51	05104620000344	AA97220-01 05104620000344 05 N/A Serum-1 8 / Day 1 333h
05	N/A	8 / Day 1 0 333h	74485 699	47162 395	1 579345	1	2 23	50	05104620000360	AA97220-01 05104620000360 05 N/A Serum-1 8 / Day 1 333h
05	N/A	8 / Day 1 0 333h	113678 528	45653 357	2 490037	1	3 50	53	05104620000376	AA97220-01 05104620000376 05 N/A Serum-1 8 / Day 1 333h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
05	N/A	8 / Day 1 0 333h	298938 891	53686 412	5 568241	1	7 80	54	05104620000392	AA97220-01 05104620000392 05 N/A Serum- 1 8 / Day 1 333h
05	N/A	9 / Day 1 0 5h	76532 884	50417 145	1 517993	1	2 14	55	05104620000345	AA97220-01 05104620000345 05 N/A Serum- 1 9 / Day 1 5h
05	N/A	9 / Day 1 0 5h	82010 373	46481 467	1 764367	1	2 49	56	05104620000361	AA97220-01 05104620000361 05 N/A Serum- 1 9 / Day 1 5h
05	N/A	9 / Day 1 0 5h	158192 969	59091 212	2 677098	1	3 76	57	05104620000377	AA97220-01 05104620000377 05 N/A Serum- 1 9 / Day 1 5h
05	N/A	9 / Day 1 0 5h	230772 29	48234 61	4 784371	1	6 70	58	05104620000393	AA97220-01 05104620000393 05 N/A Serum- 1 9 / Day 1 5h
05	N/A	10 / Day 1 0 75h	80360 065	46618 912	1 723765	1	2 43	60	05104620000346	AA97220-01 05104620000346 05 N/A Serum- 1 10 / Day 1 75h
05	N/A	10 / Day 1 0 75h	81359 942	49511 633	1 643249	1	2 32	61	05104620000362	AA97220-01 05104620000362 05 N/A Serum- 1 10 / Day 1 75h
05	N/A	10 / Day 1 0 75h	105425 919	46418 933	2 271184	1	3 19	62	05104620000378	AA97220-01 05104620000378 05 N/A Serum- 1 10 / Day 1 75h
05	N/A	10 / Day 1 0 75h	195084 082	44868 707	4 347887	1	6 09	59	05104620000394	AA97220-01 05104620000394 05 N/A Serum- 1 10 / Day 1 75h
05	N/A	11 / Day 1 1h	73032 717	46116 743	1 583649	1	2 23	66	05104620000347	AA97220-01 05104620000347 05 N/A Serum- 1 11 / Day 1 1h
05	N/A	11 / Day 1 1h	89075 51	49790 445	1 789008	1	2 52	67	05104620000363	AA97220-01 05104620000363 05 N/A Serum- 1 11 / Day 1 1h
05	N/A	11 / Day 1 1h	106817 424	51380 402	2 078953	1	2 93	64	05104620000379	AA97220-01 05104620000379 05 N/A Serum- 1 11 / Day 1 1h
05	N/A	11 / Day 1 1h	171361 919	45759 626	3 744828	1	5 25	65	05104620000395	AA97220-01 05104620000395 05 N/A Serum- 1 11 / Day 1 1h
05	N/A	12 / Day 1 1 25h	72774 162	47349 479	1 536958	1	2 17	70	05104620000348	AA97220-01 05104620000348 05 N/A Serum- 1 12 / Day 1 1 25h
05	N/A	12 / Day 1 1 25h	78299 22	51080 607	1 532856	1	2 16	69	05104620000364	AA97220-01 05104620000364 05 N/A Serum- 1 12 / Day 1 1 25h
05	N/A	12 / Day 1 1 25h	94731 56	45954 347	2 061428	1	2 90	68	05104620000380	AA97220-01 05104620000380 05 N/A Serum- 1 12 / Day 1 1 25h
05	N/A	12 / Day 1 1 25h	147829 34	43355 885	3 409672	1	4 78	71	05104620000396	AA97220-01 05104620000396 05 N/A Serum- 1 12 / Day 1 1 25h
05	N/A	13 / Day 1 1 5h	61177 422	50108 362	1 220902	1	1 73	75	05104620000349	AA97220-01 05104620000349 05 N/A Serum- 1 13 / Day 1 1 5h
05	N/A	13 / Day 1 1 5h	75142 091	48578 369	1 546822	1	2 18	73	05104620000365	AA97220-01 05104620000365 05 N/A Serum- 1 13 / Day 1 1 5h
05	N/A	13 / Day 1 1 5h	84610 065	45168 253	1 873220	1	2 64	76	05104620000381	AA97220-01 05104620000381 05 N/A Serum- 1 13 / Day 1 1 5h
05	N/A	13 / Day 1 1 5h	147111 862	51177 155	2 874561	1	4 04	72	05104620000397	AA97220-01 05104620000397 05 N/A Serum- 1 13 / Day 1 1 5h
05	N/A	14 / Day 1 2h	61443 755	50143 41	1 225361	1	1 73	79	05104620000350	AA97220-01 05104620000350 05 N/A Serum- 1 14 / Day 1 2h
05	N/A	14 / Day 1 2h	68516 314	52932 53	1 294408	1	1 83	78	05104620000366	AA97220-01 05104620000366 05 N/A Serum- 1 14 / Day 1 2h
05	N/A	14 / Day 1 2h	85010 448	53175 8	1 598668	1	2 26	80	05104620000382	AA97220-01 05104620000382 05 N/A Serum- 1 14 / Day 1 2h
05	N/A	14 / Day 1 2h	135962 106	52461 747	2 591643	1	3 64	77	05104620000398	AA97220-01 05104620000398 05 N/A Serum- 1 14 / Day 1 2h
05	N/A	15 / Day 1 2 5h	54582 195	50231 735	1 086608	1	1 54	82	05104620000351	AA97220-01 05104620000351 05 N/A Serum- 1 15 / Day 1 2 5h
05	N/A	15 / Day 1 2 5h	52994 056	53673 299	0 987345	1	1 40	83	05104620000367	AA97220-01 05104620000367 05 N/A Serum- 1 15 / Day 1 2 5h
05	N/A	15 / Day 1 2 5h	68315 987	49919 197	1 368531	1	1 93	81	05104620000383	AA97220-01 05104620000383 05 N/A Serum- 1 15 / Day 1 2 5h
05	N/A	15 / Day 1 2 5h	113364 967	48869 069	2 319769	1	3 26	84	05104620000399	AA97220-01 05104620000399 05 N/A Serum- 1 15 / Day 1 2 5h
05	N/A	16 / Day 1 3h	41618 799	45224 536	0 920270	1	1 31	85	05104620000352	AA97220-01 05104620000352 05 N/A Serum- 1 16 / Day 1 3h
05	N/A	16 / Day 1 3h	44354 819	48394 04	0 916535	1	1 30	87	05104620000368	AA97220-01 05104620000368 05 N/A Serum- 1 16 / Day 1 3h
05	N/A	16 / Day 1 3h	64593 329	51660 734	1 250337	1	1 77	86	05104620000384	AA97220-01 05104620000384 05 N/A Serum- 1 16 / Day 1 3h
05	N/A	16 / Day 1 3h	104171 588	51719 944	2 014147	1	2 84	88	05104620000400	AA97220-01 05104620000400 05 N/A Serum- 1 16 / Day 1 3h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0.500 (Lowest Standard)

AAR - Concentration Found is Greater than 50.0 (Highest Standard)

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 7
 Serum, Concentration of Nicotine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		0	154855 438	0 000000	-0 0373		-0 00600	-738 3
9	0 00		3583 218	225394 078	0 015898	0 0253			
10	0 500	4 00000	32878 008	235148 545	0 139818	0 513	2 6		
11	1 00	1 00000	56309 115	221427 002	0 254301	0 963	-3 7		
12	2 00	0 250000	117906 538	234739 46	0 502287	1 94	-3 0		
13	4 00	0 0625000	196779 343	194327 175	1 012619	3 95	-1 3		
14	8 00	0 0156250	461629 588	221350 39	2 085515	8 17	2 1		
15	10 0	0 0100000	568765 46	221410 142	2 568832	10 1	1 0		
16	20 0	0 00250000	1176453 043	225846 892	5 209073	20 5	2 5		
17	40 0	0 000625000	2402514 997	234053 243	10 264823	40 3	0 8		
18	50 0	0 000400000	2712199 799	213949 998	12 676793	49 8	-0 4		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:
 Slope = 0 254207883
 Intercept = 0 00947099876
 R-Squared = 0 9993

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)
 AAR - Concentration Found is Greater than 50 0 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 7
Serum, Concentration of Nicotine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	2432263 909	185124 124	13 138557	1	51 6		50 6		2 5
2	0 00	2213730 42	181406 857	12 203124	1	48 0				
3	0 00	2342941 325	183484 153	12 769175	1	50 2				
4	0 00	2451864 845	188327 765	13 019136	1	51 2				
5	0 00	2266893 493	175305 98	12 931068	1	50 8				
91	0 00	2618961 224	199836 741	13 105504	1	51 5				
92	0 00	2539381 063	195954 243	12 959051	1	50 9				
30	1 50	89347 483	232989 132	0 383483	1	1 47	-2 0	1 43	-4 7	4 0
63	1 50	89260 914	245505 177	0 363581	1	1 39	-7 3			
41	8 00	416360 605	222328 684	1 872726	1	7 33	-8 4	7 56	-5 5	4 2
74	8 00	350291 235	176177 884	1 988282	1	7 78	-2 8			
52	37 5	2057340 137	219011 286	9 393763	1	36 9	-1 6	36 9	-1 6	0 2
89	37 5	1913990 878	204229 903	9 371746	1	36 8	-1 9			

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)
AAR - Concentration Found is Greater than 50 0 (Highest Standard)

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 7
Serum, Concentration of Nicotine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
05	N/A	1 / Day 1 -0 0333h	63691 028	213688 251	0 298056	1	1 14	20	05104620000321	AA97220-01 05104620000321 05 N/A Serum-1 1 / Day 1 - 0333h
05	N/A	2 / Day 1 0h	68233 225	231685 203	0 294508	1	1 12	21	05104620000322	AA97220-01 05104620000322 05 N/A Serum-1 2 / Day 1 0h
05	N/A	3 / Day 1 0 05h	67290 342	230545 313	0 291875	1	1 11	22	05104620000323	AA97220-01 05104620000323 05 N/A Serum-1 3 / Day 1 05h
05	N/A	4 / Day 1 0 0833h	81977 099	229034 127	0 357925	1	1 37	23	05104620000324	AA97220-01 05104620000324 05 N/A Serum-1 4 / Day 1 0833h
05	N/A	5 / Day 1 0 125h	108244 929	230170 758	0 470281	1	1 81	24	05104620000325	AA97220-01 05104620000325 05 N/A Serum-1 5 / Day 1 125h
05	N/A	6 / Day 1 0 1667h	104854 302	212504 317	0 493422	1	1 90	25	05104620000326	AA97220-01 05104620000326 05 N/A Serum-1 6 / Day 1 1667h
05	N/A	7 / Day 1 0 25h	154886 957	213743 39	0 724640	1	2 81	26	05104620000327	AA97220-01 05104620000327 05 N/A Serum-1 7 / Day 1 25h
05	N/A	8 / Day 1 0 333h	168977 964	239419 185	0 705783	1	2 74	27	05104620000328	AA97220-01 05104620000328 05 N/A Serum-1 8 / Day 1 333h
05	N/A	9 / Day 1 0 5h	166716 158	225490 537	0 739349	1	2 87	28	05104620000329	AA97220-01 05104620000329 05 N/A Serum-1 9 / Day 1 5h
05	N/A	10 / Day 1 0 75h	189040 762	235480 347	0 802788	1	3 12	29	05104620000330	AA97220-01 05104620000330 05 N/A Serum-1 10 / Day 1 75h
05	N/A	11 / Day 1 1h	170224 643	223031 008	0 763233	1	2 97	31	05104620000331	AA97220-01 05104620000331 05 N/A Serum-1 11 / Day 1 1h
05	N/A	12 / Day 1 1 25h	157500 163	239510 337	0 657592	1	2 55	32	05104620000332	AA97220-01 05104620000332 05 N/A Serum-1 12 / Day 1 25h
05	N/A	13 / Day 1 1 5h	153109 898	237876 382	0 643653	1	2 49	33	05104620000333	AA97220-01 05104620000333 05 N/A Serum-1 13 / Day 1 1 5h
05	N/A	14 / Day 1 2h	153403 3	235797 421	0 650572	1	2 52	34	05104620000334	AA97220-01 05104620000334 05 N/A Serum-1 14 / Day 1 2h
05	N/A	15 / Day 1 2 5h	142687 831	237796 035	0 600043	1	2 32	35	05104620000335	AA97220-01 05104620000335 05 N/A Serum-1 15 / Day 1 2 5h
05	N/A	16 / Day 1 3h	123625 028	255547 02	0 483766	1	1 87	36	05104620000336	AA97220-01 05104620000336 05 N/A Serum-1 16 / Day 1 3h
06	N/A	1 / Day 1 -0 0333h	18412 975	208377 793	0 088363	1	BLQ<(0 500)	37	05104620000433	AA97220-01 05104620000433 06 N/A Serum-1 1 / Day 1 - 0333h
06	N/A	1 / Day 1 -0 0333h	20164 43	213521 677	0 094437	1	BLQ<(0 500)	38	05104620000449	AA97220-01 05104620000449 06 N/A Serum-1 1 / Day 1 - 0333h
06	N/A	1 / Day 1 -0 0333h	29770 68	221184 864	0 134596	1	BLQ<(0 500)	39	05104620000465	AA97220-01 05104620000465 06 N/A Serum-1 1 / Day 1 - 0333h
06	N/A	2 / Day 1 0h	16406 075	229339 834	0 071536	1	BLQ<(0 500)	42	05104620000434	AA97220-01 05104620000434 06 N/A Serum-1 2 / Day 1 0h
06	N/A	2 / Day 1 0h	19981 138	230159 903	0 086814	1	BLQ<(0 500)	40	05104620000450	AA97220-01 05104620000450 06 N/A Serum-1 2 / Day 1 0h
06	N/A	2 / Day 1 0h	28830 812	235479 757	0 122434	1	BLQ<(0 500)	43	05104620000466	AA97220-01 05104620000466 06 N/A Serum-1 2 / Day 1 0h
06	N/A	3 / Day 1 0 05h	66796 328	241842 737	0 276197	1	1 05	44	05104620000435	AA97220-01 05104620000435 06 N/A Serum-1 3 / Day 1 05h
06	N/A	3 / Day 1 0 05h	23843 792	202152 133	0 117950	1	BLQ<(0 500)	45	05104620000451	AA97220-01 05104620000451 06 N/A Serum-1 3 / Day 1 05h
06	N/A	3 / Day 1 0 05h	154212 075	222684 898	0 692512	1	2 69	46	05104620000467	AA97220-01 05104620000467 06 N/A Serum-1 3 / Day 1 05h
06	N/A	4 / Day 1 0 0833h	94553 588	214536 365	0 440735	1	1 70	47	05104620000436	AA97220-01 05104620000436 06 N/A Serum-1 4 / Day 1 0833h
06	N/A	4 / Day 1 0 0833h	28997 648	217165 765	0 133528	1	BLQ<(0 500)	49	05104620000452	AA97220-01 05104620000452 06 N/A Serum-1 4 / Day 1 0833h
06	N/A	4 / Day 1 0 0833h	236004 112	219625 305	1 074576	1	4 19	48	05104620000468	AA97220-01 05104620000468 06 N/A Serum-1 4 / Day 1 0833h
06	N/A	5 / Day 1 0 125h	106264 395	200427 52	0 530189	1	2 05	50	05104620000437	AA97220-01 05104620000437 06 N/A Serum-1 5 / Day 1 125h
06	N/A	5 / Day 1 0 125h	41483 437	205411 348	0 201953	1	0 757	53	05104620000453	AA97220-01 05104620000453 06 N/A Serum-1 5 / Day 1 125h
06	N/A	5 / Day 1 0 125h	293537 776	182053 44	1 612371	1	6 31	51	05104620000469	AA97220-01 05104620000469 06 N/A Serum-1 5 / Day 1 125h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
06	N/A	6 / Day 1 0 1667h	117090 862	259890 125	0 450540	1	1 74	55	05104620000438	AA97220-01 05104620000438 06 N/A Serum-1 6 / Day 1 1667h
06	N/A	6 / Day 1 0 1667h	60819 013	214195 142	0 283942	1	1 08	54	05104620000454	AA97220-01 05104620000454 06 N/A Serum-1 6 / Day 1 1667h
06	N/A	6 / Day 1 0 1667h	505178 253	236799 501	2 133359	1	8 35	56	05104620000470	AA97220-01 05104620000470 06 N/A Serum-1 6 / Day 1 1667h
06	N/A	7 / Day 1 0 25h	114025 577	269462 661	0 423159	1	1 63	59	05104620000439	AA97220-01 05104620000439 06 N/A Serum-1 7 / Day 1 25h
06	N/A	7 / Day 1 0 25h	105479 753	245232 522	0 430121	1	1 65	57	05104620000455	AA97220-01 05104620000455 06 N/A Serum-1 7 / Day 1 25h
06	N/A	7 / Day 1 0 25h	329738 978	231403 929	1 424950	1	5 57	58	05104620000471	AA97220-01 05104620000471 06 N/A Serum-1 7 / Day 1 25h
06	N/A	8 / Day 1 0 333h	118377 163	235453 565	0 502762	1	1 94	61	05104620000440	AA97220-01 05104620000440 06 N/A Serum-1 8 / Day 1 333h
06	N/A	8 / Day 1 0 333h	99863 505	245605 942	0 406601	1	1 56	60	05104620000456	AA97220-01 05104620000456 06 N/A Serum-1 8 / Day 1 333h
06	N/A	8 / Day 1 0 333h	259551 108	191876 103	1 352702	1	5 28	62	05104620000472	AA97220-01 05104620000472 06 N/A Serum-1 8 / Day 1 333h
06	N/A	9 / Day 1 0 5h	109817 485	225871 668	0 486194	1	1 88	64	05104620000441	AA97220-01 05104620000441 06 N/A Serum-1 9 / Day 1 5h
06	N/A	9 / Day 1 0 5h	103630 959	259915 663	0 398710	1	1 53	66	05104620000457	AA97220-01 05104620000457 06 N/A Serum-1 9 / Day 1 5h
06	N/A	9 / Day 1 0 5h	266025 173	242574 393	1 096675	1	4 28	65	05104620000473	AA97220-01 05104620000473 06 N/A Serum-1 9 / Day 1 5h
06	N/A	10 / Day 1 0 75h	82142 777	244452 735	0 336027	1	1 28	69	05104620000442	AA97220-01 05104620000442 06 N/A Serum-1 10 / Day 1 75h
06	N/A	10 / Day 1 0 75h	97204 857	245768 688	0 395514	1	1 52	68	05104620000458	AA97220-01 05104620000458 06 N/A Serum-1 10 / Day 1 75h
06	N/A	10 / Day 1 0 75h	240760 271	237483 589	1 013798	1	3 95	67	05104620000474	AA97220-01 05104620000474 06 N/A Serum-1 10 / Day 1 75h
06	N/A	11 / Day 1 1h	91810 594	248974 735	0 368755	1	1 41	70	05104620000443	AA97220-01 05104620000443 06 N/A Serum-1 11 / Day 1 1h
06	N/A	11 / Day 1 1h	88736 795	253924 762	0 349461	1	1 34	72	05104620000459	AA97220-01 05104620000459 06 N/A Serum-1 11 / Day 1 1h
06	N/A	11 / Day 1 1h	217117 81	249154 9	0 871417	1	3 39	71	05104620000475	AA97220-01 05104620000475 06 N/A Serum-1 11 / Day 1 1h
06	N/A	12 / Day 1 1 25h	60758 982	205950 412	0 295018	1	1 12	73	05104620000444	AA97220-01 05104620000444 06 N/A Serum-1 12 / Day 1 1 25h
06	N/A	12 / Day 1 1 25h	69827 605	219581 15	0 318004	1	1 21	76	05104620000460	AA97220-01 05104620000460 06 N/A Serum-1 12 / Day 1 1 25h
06	N/A	12 / Day 1 1 25h	174388 163	207022 935	0 842362	1	3 28	75	05104620000476	AA97220-01 05104620000476 06 N/A Serum-1 12 / Day 1 1 25h
06	N/A	13 / Day 1 1 5h	65506 473	220092 172	0 297632	1	1 13	78	05104620000445	AA97220-01 05104620000445 06 N/A Serum-1 13 / Day 1 1 5h
06	N/A	13 / Day 1 1 5h	69727 975	232917 895	0 299367	1	1 14	79	05104620000461	AA97220-01 05104620000461 06 N/A Serum-1 13 / Day 1 1 5h
06	N/A	13 / Day 1 1 5h	192959 338	225176 367	0 856925	1	3 33	77	05104620000477	AA97220-01 05104620000477 06 N/A Serum-1 13 / Day 1 1 5h
06	N/A	14 / Day 1 2h	61753 107	199050 526	0 310238	1	1 18	81	05104620000446	AA97220-01 05104620000446 06 N/A Serum-1 14 / Day 1 2h
06	N/A	14 / Day 1 2h	73956 877	247056 592	0 299352	1	1 14	82	05104620000462	AA97220-01 05104620000462 06 N/A Serum-1 14 / Day 1 2h
06	N/A	14 / Day 1 2h	152329 592	229890 682	0 662618	1	2 57	80	05104620000478	AA97220-01 05104620000478 06 N/A Serum-1 14 / Day 1 2h
06	N/A	15 / Day 1 2 5h	48585 692	210088 345	0 231263	1	0 872	84	05104620000447	AA97220-01 05104620000447 06 N/A Serum-1 15 / Day 1 2 5h
06	N/A	15 / Day 1 2 5h	45913 473	208605 455	0 220097	1	0 829	83	05104620000463	AA97220-01 05104620000463 06 N/A Serum-1 15 / Day 1 2 5h
06	N/A	15 / Day 1 2 5h	110578 652	190726 928	0 579775	1	2 24	85	05104620000479	AA97220-01 05104620000479 06 N/A Serum-1 15 / Day 1 2 5h
06	N/A	16 / Day 1 3h	45664 27	221086 615	0 206545	1	0 775	88	05104620000448	AA97220-01 05104620000448 06 N/A Serum-1 16 / Day 1 3h
06	N/A	16 / Day 1 3h	39229 523	192749 887	0 203526	1	0 763	87	05104620000464	AA97220-01 05104620000464 06 N/A Serum-1 16 / Day 1 3h
06	N/A	16 / Day 1 3h	83951 868	194491 523	0 431648	1	1 66	86	05104620000480	AA97220-01 05104620000480 06 N/A Serum-1 16 / Day 1 3h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0.500 (Lowest Standard)

AAR - Concentration Found is Greater than 50.0 (Highest Standard)

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 8
 Serum, Concentration of Nicotine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		0	225963 327	0 000000	-0 0934		-0 0934	0 0
9	0 00		0	205158 367	0 000000	-0 0934			
10	0 500	4 00000	32425 383	229533 803	0 141266	0 479	-4 2		
11	1 00	1 00000	61701 695	210511 145	0 293104	1 09	9 0		
12	2 00	0 250000	118985 263	227402 677	0 523236	2 03	1 5		
13	4 00	0 0625000	235592 008	238801 442	0 986560	3 91	-2 3		
14	8 00	0 0156250	426329 619	237948 352	1 791690	7 17	-10 4		
15	10 0	0 0100000	620017 508	255248 809	2 429071	9 75	-2 5		
16	20 0	0 00250000	1049912 63	204942 8	5 122954	20 7	3 5		
17	40 0	0 000625000	2222562 893	210475 96	10 559700	42 7	6 8		
18	50 0	0 000400000	2920891 767	240074 583	12 166601	49 2	-1 6		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:

Slope = 0 246720179

Intercept = 0 0230351250

R-Squared = 0 9951

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)

AAR - Concentration Found is Greater than 50 0 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 8
Serum, Concentration of Nicotine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	2904810 705	233036 182	12 465063	1	50 4		51 0		1 7
2	0 00	2818072 648	229815 851	12 262308	1	49 6				
3	0 00	2752341 142	216038 23	12 740065	1	51 5				
4	0 00	2877418 63	223592 621	12 869023	1	52 1				
5	0 00	2567975 05	205206 08	12 514128	1	50 6				
91	0 00	3111980 05	243400 385	12 785436	1	51 7				
92	0 00	3092388 937	246107 843	12 565178	1	50 8				
30	1 50	89796 132	239274 988	0 375284	1	1 43	-4 7	1 81	20 7	29 3
63	1 50	81303 832	144881 857	0 561173	1	2 18	45 3			
41	8 00	444616 704	242740 8	1 831652	1	7 33	-8 4	7 43	-7 1	1 9
74	8 00	462199 628	245796 4	1 880417	1	7 53	-5 9			
52	37 5	1947157 615	203802 47	9 554141	1	38 6	2 9	38 6	2 9	0 0
89	37 5	2029304 46	212547 513	9 547533	1	38 6	2 9			

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)
AAR - Concentration Found is Greater than 50 0 (Highest Standard)

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 8
Serum, Concentration of Nicotine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
06	N/A	1 / Day 1 -0 0333h	15462 748	242424 302	0 063784	1	BLQ<(0 500)	21	05104620000401	AA97220-01 05104620000401 06 N/A Serum-1 1 / Day 1 - 0333h
06	N/A	1 / Day 1 -0 0333h	20733 887	216125 152	0 095935	1	BLQ<(0 500)	20	05104620000417	AA97220-01 05104620000417 06 N/A Serum-1 1 / Day 1 - 0333h
06	N/A	2 / Day 1 0h	17807 805	233308 163	0 076327	1	BLQ<(0 500)	22	05104620000402	AA97220-01 05104620000402 06 N/A Serum-1 2 / Day 1 0h
06	N/A	2 / Day 1 0h	20599 092	201466 947	0 102246	1	BLQ<(0 500)	23	05104620000418	AA97220-01 05104620000418 06 N/A Serum-1 2 / Day 1 0h
06	N/A	3 / Day 1 0 05h	24338 523	207328 963	0 117391	1	BLQ<(0 500)	24	05104620000403	AA97220-01 05104620000403 06 N/A Serum-1 3 / Day 1 05h
06	N/A	3 / Day 1 0 05h	22302 363	224102 262	0 099519	1	BLQ<(0 500)	25	05104620000419	AA97220-01 05104620000419 06 N/A Serum-1 3 / Day 1 05h
06	N/A	4 / Day 1 0 0833h	31902 483	236650 585	0 134808	1	BLQ<(0 500)	27	05104620000404	AA97220-01 05104620000404 06 N/A Serum-1 4 / Day 1 0833h
06	N/A	4 / Day 1 0 0833h	19165 208	220096 137	0 087077	1	BLQ<(0 500)	26	05104620000420	AA97220-01 05104620000420 06 N/A Serum-1 4 / Day 1 0833h
06	N/A	5 / Day 1 0 125h	36086 603	239760 378	0 150511	1	0 517	29	05104620000405	AA97220-01 05104620000405 06 N/A Serum-1 5 / Day 1 125h
06	N/A	5 / Day 1 0 125h	29723 572	228844 578	0 129885	1	BLQ<(0 500)	28	05104620000421	AA97220-01 05104620000421 06 N/A Serum-1 5 / Day 1 125h
06	N/A	6 / Day 1 0 1667h	38408 595	237651 707	0 161617	1	0 562	32	05104620000406	AA97220-01 05104620000406 06 N/A Serum-1 6 / Day 1 1667h
06	N/A	6 / Day 1 0 1667h	38555 155	225961 853	0 170627	1	0 598	31	05104620000422	AA97220-01 05104620000422 06 N/A Serum-1 6 / Day 1 1667h
06	N/A	7 / Day 1 0 25h	45703 995	219273 815	0 208433	1	0 751	34	05104620000407	AA97220-01 05104620000407 06 N/A Serum-1 7 / Day 1 25h
06	N/A	7 / Day 1 0 25h	48575 363	225765 808	0 215158	1	0 779	33	05104620000423	AA97220-01 05104620000423 06 N/A Serum-1 7 / Day 1 25h
06	N/A	8 / Day 1 0 333h	59352 627	207164 194	0 286500	1	1 07	35	05104620000408	AA97220-01 05104620000408 06 N/A Serum-1 8 / Day 1 333h
06	N/A	8 / Day 1 0 333h	73383 758	243644 757	0 301192	1	1 13	36	05104620000424	AA97220-01 05104620000424 06 N/A Serum-1 8 / Day 1 333h
06	N/A	9 / Day 1 0 5h	60022 153	234831 629	0 255597	1	0 943	38	05104620000409	AA97220-01 05104620000409 06 N/A Serum-1 9 / Day 1 5h
06	N/A	9 / Day 1 0 5h	73379 275	219935 083	0 333641	1	1 26	37	05104620000425	AA97220-01 05104620000425 06 N/A Serum-1 9 / Day 1 5h
06	N/A	10 / Day 1 0 75h	84113 682	222656 182	0 377774	1	1 44	39	05104620000410	AA97220-01 05104620000410 06 N/A Serum-1 10 / Day 1 75h
06	N/A	10 / Day 1 0 75h	68413 492	252195 572	0 271272	1	1 01	40	05104620000426	AA97220-01 05104620000426 06 N/A Serum-1 10 / Day 1 75h
06	N/A	11 / Day 1 1h	83299 298	263598 662	0 316008	1	1 19	43	05104620000411	AA97220-01 05104620000411 06 N/A Serum-1 11 / Day 1 1h
06	N/A	11 / Day 1 1h	62058 163	234274 098	0 264896	1	0 980	42	05104620000427	AA97220-01 05104620000427 06 N/A Serum-1 11 / Day 1 1h
06	N/A	12 / Day 1 1 25h	49952 052	212299 723	0 235290	1	0 860	45	05104620000412	AA97220-01 05104620000412 06 N/A Serum-1 12 / Day 1 1 25h
06	N/A	12 / Day 1 1 25h	68114 955	247122 582	0 275632	1	1 02	44	05104620000428	AA97220-01 05104620000428 06 N/A Serum-1 12 / Day 1 1 25h
06	N/A	13 / Day 1 1 5h	68772 962	258375 635	0 266174	1	0 985	47	05104620000413	AA97220-01 05104620000413 06 N/A Serum-1 13 / Day 1 1 5h
06	N/A	13 / Day 1 1 5h	67387 588	249501 434	0 270089	1	1 00	46	05104620000429	AA97220-01 05104620000429 06 N/A Serum-1 13 / Day 1 1 5h
06	N/A	14 / Day 1 2h	46679 757	232298 646	0 200947	1	0 721	49	05104620000414	AA97220-01 05104620000414 06 N/A Serum-1 14 / Day 1 2h
06	N/A	14 / Day 1 2h	51261 277	227855 217	0 224973	1	0 818	48	05104620000430	AA97220-01 05104620000430 06 N/A Serum-1 14 / Day 1 2h
06	N/A	15 / Day 1 2 5h	36545 998	205958 442	0 177444	1	0 626	50	05104620000415	AA97220-01 05104620000415 06 N/A Serum-1 15 / Day 1 2 5h
06	N/A	15 / Day 1 2 5h	40531 552	213378 452	0 189951	1	0 677	51	05104620000431	AA97220-01 05104620000431 06 N/A Serum-1 15 / Day 1 2 5h
06	N/A	16 / Day 1 3h	33699 267	201759 735	0 167027	1	0 584	53	05104620000416	AA97220-01 05104620000416 06 N/A Serum-1 16 / Day 1 3h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
06	N/A	16 / Day 1 3h	40998 778	250602 121	0 163601	1	0 570	54	05104620000432	AA97220-01 05104620000432 06 N/A Serum-1 16 / Day 1 3h
07	N/A	1 / Day 1 -0 0333h	53558 553	216182 183	0 247747	1	0 911	55	05104620000545	AA97220-01 05104620000545 07 N/A Serum-1 1 / Day 1 - 0333h
07	N/A	2 / Day 1 0h	35841 022	218126 91	0 164313	1	0 573	56	05104620000546	AA97220-01 05104620000546 07 N/A Serum-1 2 / Day 1 0h
07	N/A	3 / Day 1 0 05h	207376 692	235466 967	0 880704	1	3 48	57	05104620000547	AA97220-01 05104620000547 07 N/A Serum-1 3 / Day 1 05h
07	N/A	4 / Day 1 0 0833h	313250 055	221190 935	1 416198	1	5 65	58	05104620000548	AA97220-01 05104620000548 07 N/A Serum-1 4 / Day 1 0833h
07	N/A	5 / Day 1 0 125h	504488 35	217373 523	2 320836	1	9 31	59	05104620000549	AA97220-01 05104620000549 07 N/A Serum-1 5 / Day 1 125h
07	N/A	6 / Day 1 0 1667h	596993 342	236572 083	2 523516	1	10 1	60	05104620000550	AA97220-01 05104620000550 07 N/A Serum-1 6 / Day 1 1667h
07	N/A	7 / Day 1 0 25h	588955 225	256692 165	2 294403	1	9 21	61	05104620000551	AA97220-01 05104620000551 07 N/A Serum-1 7 / Day 1 25h
07	N/A	8 / Day 1 0 333h	397676 152	211877 587	1 876915	1	7 51	62	05104620000552	AA97220-01 05104620000552 07 N/A Serum-1 8 / Day 1 333h
07	N/A	9 / Day 1 0 5h	362408 434	212359 397	1 706581	1	6 82	64	05104620000553	AA97220-01 05104620000553 07 N/A Serum-1 9 / Day 1 5h
07	N/A	10 / Day 1 0 75h	304973 855	213119 23	1 431001	1	5 71	65	05104620000554	AA97220-01 05104620000554 07 N/A Serum-1 10 / Day 1 75h
07	N/A	11 / Day 1 1h	283677 942	221027 432	1 283451	1	5 11	66	05104620000555	AA97220-01 05104620000555 07 N/A Serum-1 11 / Day 1 1h
07	N/A	12 / Day 1 1 25h	284386 355	239704 78	1 186403	1	4 72	67	05104620000556	AA97220-01 05104620000556 07 N/A Serum-1 12 / Day 1 1 25h
07	N/A	13 / Day 1 1 5h	272666 787	242918 947	1 122460	1	4 46	68	05104620000557	AA97220-01 05104620000557 07 N/A Serum-1 13 / Day 1 1 5h
07	N/A	14 / Day 1 2h	234331 621	255724 053	0 916346	1	3 62	69	05104620000558	AA97220-01 05104620000558 07 N/A Serum-1 14 / Day 1 2h
07	N/A	15 / Day 1 2 5h	195717 817	236540 917	0 827416	1	3 26	70	05104620000559	AA97220-01 05104620000559 07 N/A Serum-1 15 / Day 1 2 5h
07	N/A	16 / Day 1 3h	134320 535	225379 455	0 595975	1	2 32	71	05104620000560	AA97220-01 05104620000560 07 N/A Serum-1 16 / Day 1 3h
08	N/A	1 / Day 1 -0 0333h	67998 052	240509 984	0 282724	1	1 05	72	05104620000625	AA97220-01 05104620000625 08 N/A Serum-1 1 / Day 1 - 0333h
08	N/A	2 / Day 1 0h	80404 999	259464 449	0 309888	1	1 16	73	05104620000626	AA97220-01 05104620000626 08 N/A Serum-1 2 / Day 1 0h
08	N/A	3 / Day 1 0 05h	355261 27	283837 11	1 251638	1	4 98	75	05104620000627	AA97220-01 05104620000627 08 N/A Serum-1 3 / Day 1 05h
08	N/A	4 / Day 1 0 0833h	482183 595	241848 822	1 993740	1	7 99	76	05104620000628	AA97220-01 05104620000628 08 N/A Serum-1 4 / Day 1 0833h
08	N/A	5 / Day 1 0 125h	569480 739	243273 835	2 340904	1	9 39	77	05104620000629	AA97220-01 05104620000629 08 N/A Serum-1 5 / Day 1 125h
08	N/A	6 / Day 1 0 1667h	770797 445	317215 363	2 429887	1	9 76	78	05104620000630	AA97220-01 05104620000630 08 N/A Serum-1 6 / Day 1 1667h
08	N/A	7 / Day 1 0 25h	596577 582	240985 133	2 475578	1	9 94	79	05104620000631	AA97220-01 05104620000631 08 N/A Serum-1 7 / Day 1 25h
08	N/A	8 / Day 1 0 333h	695806 04	285039 856	2 441083	1	9 80	80	05104620000632	AA97220-01 05104620000632 08 N/A Serum-1 8 / Day 1 333h
08	N/A	9 / Day 1 0 5h	502528 451	256195 625	1 961503	1	7 86	81	05104620000633	AA97220-01 05104620000633 08 N/A Serum-1 9 / Day 1 5h
08	N/A	10 / Day 1 0 75h	430769 637	249206 889	1 728562	1	6 91	82	05104620000634	AA97220-01 05104620000634 08 N/A Serum-1 10 / Day 1 75h
08	N/A	11 / Day 1 1h	500748 952	303551 833	1 649632	1	6 59	83	05104620000635	AA97220-01 05104620000635 08 N/A Serum-1 11 / Day 1 1h
08	N/A	12 / Day 1 1 25h	359722 692	236007 805	1 524198	1	6 08	84	05104620000636	AA97220-01 05104620000636 08 N/A Serum-1 12 / Day 1 1 25h
08	N/A	13 / Day 1 1 5h	359750 56	251871 048	1 428312	1	5 70	85	05104620000637	AA97220-01 05104620000637 08 N/A Serum-1 13 / Day 1 1 5h
08	N/A	14 / Day 1 2h	306168 303	234398 72	1 306186	1	5 20	86	05104620000638	AA97220-01 05104620000638 08 N/A Serum-1 14 / Day 1 2h
08	N/A	15 / Day 1 2 5h	287595 515	251601 934	1 143058	1	4 54	87	05104620000639	AA97220-01 05104620000639 08 N/A Serum-1 15 / Day 1 2 5h
08	N/A	16 / Day 1 3h	170146 738	151869 562	1 120348	1	4 45	88	05104620000640	AA97220-01 05104620000640 08 N/A Serum-1 16 / Day 1 3h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0.500 (Lowest Standard)

AAR - Concentration Found is Greater than 50.0 (Highest Standard)

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 10
Serum, Concentration of Nicotine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		0	33603 923	0 000000	-0 0233		-0 0233	0 0
9	0 00		0	35003 085	0 000000	-0 0233			
10	0 500	4 00000	0	36854 347	*0 000000	*-0 0233			
11	1 00	1 00000	25504 113	35680 958	0 714782	0 986	-1 4		
12	2 00	0 250000	58094 238	39295 995	1 478376	2 06	3 0		
13	4 00	0 0625000	93237 746	32230 107	2 892877	4 06	1 5		
14	8 00	0 0156250	195013 988	34944 062	5 580748	7 86	-1 8		
15	10 0	0 0100000	215924 217	31928 393	6 762765	9 53	-4 7		
16	20 0	0 00250000	522664 219	36210 371	14 434103	20 4	2 0		
17	40 0	0 000625000	877582 64	30881 93	28 417351	40 1	0 3		
18	50 0	0 000400000	1267999 374	35372 007	35 847538	50 6	1 2		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:

Slope = 0 708255787

Intercept = 0 0164747051

R-Squared = 0 9991

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)

AAR - Concentration Found is Greater than 50 0 (Highest Standard)

Reason for Deactivation of Sample

* Rejected

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 10
Serum, Concentration of Nicotine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	1334028 973	38624 013	34 538850	1	48 7		50 0		3 9
2	0 00	1253496 995	37100 962	33 786105	1	47 7				
3	0 00	1379496 93	39144 04	35 241557	1	49 7				
4	0 00	1340329 603	38233 558	35 056366	1	49 5				
5	0 00	1262954 442	33163 41	38 082768	1	53 7				
91	0 00	1072801 881	30659 318	34 991055	1	49 4				
92	0 00	1197765 019	33043 568	36 248053	1	51 2				
30	1 50	59229 509	56010 42	1 057473	1	1 47	-2 0	1 49	-0 7	1 4
63	1 50	46912 877	43499 682	1 078465	1	1 50	0 0			
41	8 00	266640 429	50204 785	5 311056	1	7 48	-6 5	7 82	-2 3	6 1
74	8 00	265234 33	45843 618	5 785633	1	8 15	1 9			
52	37 5	1149706 937	42146 117	27 279071	1	38 5	2 7	38 0	1 3	2 0
89	37 5	836634 425	31579 152	26 493252	1	37 4	-0 3			

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1 00 (Lowest Standard)
AAR - Concentration Found is Greater than 50 0 (Highest Standard)

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 10
Serum, Concentration of Nicotine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
09	N/A	1 / Day 1 -0 0333h	35389 107	44053 208	0 803326	1	1 11	21	05104620000657	AA97220-01 05104620000657 09 N/A Serum-1 1 / Day 1 - 0333h
09	N/A	1 / Day 1 -0 0333h	36077 855	42748 965	0 843947	1	1 17	22	05104620000673	AA97220-01 05104620000673 09 N/A Serum-1 1 / Day 1 - 0333h
09	N/A	1 / Day 1 -0 0333h	39364 775	47369 86	0 831009	1	1 15	23	05104620000689	AA97220-01 05104620000689 09 N/A Serum-1 1 / Day 1 - 0333h
09	N/A	1 / Day 1 -0 0333h	29194 663	43289 968	*0 674398	1	*BLQ<(1 00)	20	05104620000705	AA97220-01 05104620000705 09 N/A Serum-1 1 / Day 1 - 0333h
09	N/A	2 / Day 1 0h	31092 068	53874 273	*0 577123	1	*BLQ<(1 00)	27	05104620000658	AA97220-01 05104620000658 09 N/A Serum-1 2 / Day 1 0h
09	N/A	2 / Day 1 0h	42321 08	52043 592	0 813185	1	1 12	26	05104620000674	AA97220-01 05104620000674 09 N/A Serum-1 2 / Day 1 0h
09	N/A	2 / Day 1 0h	36555 362	48399 487	0 755284	1	1 04	25	05104620000690	AA97220-01 05104620000690 09 N/A Serum-1 2 / Day 1 0h
09	N/A	2 / Day 1 0h	40429 08	48735 675	0 829558	1	1 15	24	05104620000706	AA97220-01 05104620000706 09 N/A Serum-1 2 / Day 1 0h
09	N/A	3 / Day 1 0 05h	103651 753	52482 236	1 974987	1	2 77	28	05104620000659	AA97220-01 05104620000659 09 N/A Serum-1 3 / Day 1 05h
09	N/A	3 / Day 1 0 05h	49764 712	50888 77	0 977911	1	1 36	29	05104620000675	AA97220-01 05104620000675 09 N/A Serum-1 3 / Day 1 05h
09	N/A	3 / Day 1 0 05h	41572 488	46880 523	0 886775	1	1 23	31	05104620000691	AA97220-01 05104620000691 09 N/A Serum-1 3 / Day 1 05h
09	N/A	3 / Day 1 0 05h	274273 12	50285 874	5 454278	1	7 68	32	05104620000707	AA97220-01 05104620000707 09 N/A Serum-1 3 / Day 1 05h
09	N/A	4 / Day 1 0 0833h	69726 33	49035 572	1 421954	1	1 98	35	05104620000660	AA97220-01 05104620000660 09 N/A Serum-1 4 / Day 1 0833h
09	N/A	4 / Day 1 0 0833h	45497 952	52664 649	0 863918	1	1 20	33	05104620000676	AA97220-01 05104620000676 09 N/A Serum-1 4 / Day 1 0833h
09	N/A	4 / Day 1 0 0833h	47422 908	51639 767	0 918341	1	1 27	36	05104620000692	AA97220-01 05104620000692 09 N/A Serum-1 4 / Day 1 0833h
09	N/A	4 / Day 1 0 0833h	375609 068	52865 333	7 105017	1	10 0	34	05104620000708	AA97220-01 05104620000708 09 N/A Serum-1 4 / Day 1 0833h
09	N/A	5 / Day 1 0 125h	87662 433	47459 498	1 847100	1	2 58	39	05104620000661	AA97220-01 05104620000661 09 N/A Serum-1 5 / Day 1 125h
09	N/A	5 / Day 1 0 125h	76177 525	59310 445	1 284386	1	1 79	40	05104620000677	AA97220-01 05104620000677 09 N/A Serum-1 5 / Day 1 125h
09	N/A	5 / Day 1 0 125h	61800 052	50845 389	1 215450	1	1 69	37	05104620000693	AA97220-01 05104620000693 09 N/A Serum-1 5 / Day 1 125h
09	N/A	5 / Day 1 0 125h	423940 526	49397 437	8 582237	1	12 1	38	05104620000709	AA97220-01 05104620000709 09 N/A Serum-1 5 / Day 1 125h
09	N/A	6 / Day 1 0 1667h	91254 716	47978 038	1 902010	1	2 66	44	05104620000662	AA97220-01 05104620000662 09 N/A Serum-1 6 / Day 1 1667h
09	N/A	6 / Day 1 0 1667h	67213 008	45344 303	1 482281	1	2 07	45	05104620000678	AA97220-01 05104620000678 09 N/A Serum-1 6 / Day 1 1667h
09	N/A	6 / Day 1 0 1667h	59110 498	52005 278	1 136625	1	1 58	43	05104620000694	AA97220-01 05104620000694 09 N/A Serum-1 6 / Day 1 1667h
09	N/A	6 / Day 1 0 1667h	372974 442	53718 162	6 943172	1	9 78	42	05104620000710	AA97220-01 05104620000710 09 N/A Serum-1 6 / Day 1 1667h
09	N/A	7 / Day 1 0 25h	136061 211	46380 34	2 933597	1	4 12	48	05104620000663	AA97220-01 05104620000663 09 N/A Serum-1 7 / Day 1 25h
09	N/A	7 / Day 1 0 25h	55740 61	43498 47	1 281438	1	1 79	47	05104620000679	AA97220-01 05104620000679 09 N/A Serum-1 7 / Day 1 25h
09	N/A	7 / Day 1 0 25h	66503 185	44086 658	1 508465	1	2 11	46	05104620000695	AA97220-01 05104620000695 09 N/A Serum-1 7 / Day 1 25h
09	N/A	7 / Day 1 0 25h	278890 525	43154 537	6 462600	1	9 10	49	05104620000711	AA97220-01 05104620000711 09 N/A Serum-1 7 / Day 1 25h
09	N/A	8 / Day 1 0 333h	90697 893	37168 273	2 440197	1	3 42	54	05104620000664	AA97220-01 05104620000664 09 N/A Serum-1 8 / Day 1 333h
09	N/A	8 / Day 1 0 333h	87485 033	41945 123	2 085702	1	2 92	50	05104620000680	AA97220-01 05104620000680 09 N/A Serum-1 8 / Day 1 333h
09	N/A	8 / Day 1 0 333h	47413 667	36477 972	1 299789	1	1 81	51	05104620000696	AA97220-01 05104620000696 09 N/A Serum-1 8 / Day 1 333h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
09	N/A	8 / Day 1 0 333h	197253 64	33789 324	5 837750	1	8 22	53	05104620000712	AA97220-01 05104620000712 09 N/A Serum-1 8 / Day 1 333h
09	N/A	9 / Day 1 0 5h	98810 522	46931 608	2 105415	1	2 95	56	05104620000665	AA97220-01 05104620000665 09 N/A Serum-1 9 / Day 1 5h
09	N/A	9 / Day 1 0 5h	86719 097	46834 291	1 851615	1	2 59	55	05104620000681	AA97220-01 05104620000681 09 N/A Serum-1 9 / Day 1 5h
09	N/A	9 / Day 1 0 5h	115628 84	47630 835	2 427605	1	3 40	57	05104620000697	AA97220-01 05104620000697 09 N/A Serum-1 9 / Day 1 5h
09	N/A	9 / Day 1 0 5h	263230 911	46805 717	5 623905	1	7 92	58	05104620000713	AA97220-01 05104620000713 09 N/A Serum-1 9 / Day 1 5h
09	N/A	10 / Day 1 0 75h	78402 797	41932 922	1 869719	1	2 62	59	05104620000666	AA97220-01 05104620000666 09 N/A Serum-1 10 / Day 1 75h
09	N/A	10 / Day 1 0 75h	94032 19	42188 09	2 228880	1	3 12	60	05104620000682	AA97220-01 05104620000682 09 N/A Serum-1 10 / Day 1 75h
09	N/A	10 / Day 1 0 75h	116470 167	44788 827	2 600429	1	3 65	61	05104620000698	AA97220-01 05104620000698 09 N/A Serum-1 10 / Day 1 75h
09	N/A	10 / Day 1 0 75h	196186 204	41602 452	4 715737	1	6 63	62	05104620000714	AA97220-01 05104620000714 09 N/A Serum-1 10 / Day 1 75h
09	N/A	11 / Day 1 1h	70199 348	43898 317	1 599135	1	2 23	67	05104620000667	AA97220-01 05104620000667 09 N/A Serum-1 11 / Day 1 1h
09	N/A	11 / Day 1 1h	90510 42	43098 398	2 100088	1	2 94	64	05104620000683	AA97220-01 05104620000683 09 N/A Serum-1 11 / Day 1 1h
09	N/A	11 / Day 1 1h	99283 348	39086 367	2 540102	1	3 56	66	05104620000699	AA97220-01 05104620000699 09 N/A Serum-1 11 / Day 1 1h
09	N/A	11 / Day 1 1h	178603 241	44109 613	4 049077	1	5 69	65	05104620000715	AA97220-01 05104620000715 09 N/A Serum-1 11 / Day 1 1h
09	N/A	12 / Day 1 1 25h	71318 377	49150 057	1 451033	1	2 03	71	05104620000668	AA97220-01 05104620000668 09 N/A Serum-1 12 / Day 1 1 25h
09	N/A	12 / Day 1 1 25h	73468 267	40765 285	1 802226	1	2 52	69	05104620000684	AA97220-01 05104620000684 09 N/A Serum-1 12 / Day 1 1 25h
09	N/A	12 / Day 1 1 25h	91146 807	46340 735	1 966883	1	2 75	68	05104620000700	AA97220-01 05104620000700 09 N/A Serum-1 12 / Day 1 1 25h
09	N/A	12 / Day 1 1 25h	174490 101	46135 355	3 782134	1	5 32	70	05104620000716	AA97220-01 05104620000716 09 N/A Serum-1 12 / Day 1 1 25h
09	N/A	13 / Day 1 1 5h	64526 162	46363 228	1 391753	1	1 94	73	05104620000669	AA97220-01 05104620000669 09 N/A Serum-1 13 / Day 1 1 5h
09	N/A	13 / Day 1 1 5h	77871 45	48553 45	1 603829	1	2 24	75	05104620000685	AA97220-01 05104620000685 09 N/A Serum-1 13 / Day 1 1 5h
09	N/A	13 / Day 1 1 5h	83307 695	41573 401	2 003870	1	2 81	76	05104620000701	AA97220-01 05104620000701 09 N/A Serum-1 13 / Day 1 1 5h
09	N/A	13 / Day 1 1 5h	159795 667	46669 917	3 423954	1	4 81	72	05104620000717	AA97220-01 05104620000717 09 N/A Serum-1 13 / Day 1 1 5h
09	N/A	14 / Day 1 2h	55373 073	40473 673	1 368126	1	1 91	79	05104620000670	AA97220-01 05104620000670 09 N/A Serum-1 14 / Day 1 2h
09	N/A	14 / Day 1 2h	58960 872	38283 059	1 540130	1	2 15	80	05104620000686	AA97220-01 05104620000686 09 N/A Serum-1 14 / Day 1 2h
09	N/A	14 / Day 1 2h	68767 032	37467 232	1 835391	1	2 57	77	05104620000702	AA97220-01 05104620000702 09 N/A Serum-1 14 / Day 1 2h
09	N/A	14 / Day 1 2h	73981 526	32194 542	2 297952	1	3 22	78	05104620000718	AA97220-01 05104620000718 09 N/A Serum-1 14 / Day 1 2h
09	N/A	15 / Day 1 2 5h	32166 11	32831 722	0 979727	1	1 36	84	05104620000671	AA97220-01 05104620000671 09 N/A Serum-1 15 / Day 1 2 5h
09	N/A	15 / Day 1 2 5h	56720 58	37668 688	1 505775	1	2 10	81	05104620000687	AA97220-01 05104620000687 09 N/A Serum-1 15 / Day 1 2 5h
09	N/A	15 / Day 1 2 5h	49264 948	31845 113	1 547018	1	2 16	83	05104620000703	AA97220-01 05104620000703 09 N/A Serum-1 15 / Day 1 2 5h
09	N/A	15 / Day 1 2 5h	83510 942	37213 741	2 244089	1	3 15	82	05104620000719	AA97220-01 05104620000719 09 N/A Serum-1 15 / Day 1 2 5h
09	N/A	16 / Day 1 3h	27255 37	29404 253	0 926919	1	1 29	87	05104620000672	AA97220-01 05104620000672 09 N/A Serum-1 16 / Day 1 3h
09	N/A	16 / Day 1 3h	40641 73	31237 213	1 301068	1	1 81	88	05104620000688	AA97220-01 05104620000688 09 N/A Serum-1 16 / Day 1 3h
09	N/A	16 / Day 1 3h	37337 922	27544 585	1 355545	1	1 89	85	05104620000704	AA97220-01 05104620000704 09 N/A Serum-1 16 / Day 1 3h
09	N/A	16 / Day 1 3h	54844 42	31202 195	1 757710	1	2 46	86	05104620000720	AA97220-01 05104620000720 09 N/A Serum-1 16 / Day 1 3h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name

Response Type = Area Ratio

BLQ - Concentration Found is Less than 1.00 (Lowest Standard)

AAR - Concentration Found is Greater than 50.0 (Highest Standard)

* - Sample Rejected

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 12
Serum, Concentration of Nicotine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		2612 099	206430 32	0 012654	0 00543		0 0217	106 0
9	0 00		4149 498	197609 975	0 020998	0 0379			
10	0 500	4 00000	28186 813	204636 273	0 137741	0 492	-1 6		
11	1 00	1 00000	61949 507	229026 008	0 270491	1 01	1 0		
12	2 00	0 250000	122910 372	223810 078	0 549173	2 09	4 5		
13	4 00	0 0625000	222430 098	217087 693	1 024609	3 95	-1 3		
14	8 00	0 0156250	436159 692	206472 463	2 112435	8 18	2 3		
15	10 0	0 0100000	512326 53	200881 453	2 550392	9 89	-1 1		
16	20 0	0 00250000	1036531 853	201418 523	5 146160	20 0	0 0		
17	40 0	0 000625000	2166441 854	209292 2	10 351279	40 3	0 8		
18	50 0	0 000400000	2585580 241	210527 963	12 281410	47 8	-4 4		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:

Slope = 0 256855346

Intercept = 0 0112593082

R-Squared = 0 9991

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)

AAR - Concentration Found is Greater than 50 0 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 12
 Serum, Concentration of Nicotine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	2650941 44	212075 96	12 499962	1	48 6		48 5		1 5
2	0 00	2640620 532	209859 092	12 582826	1	48 9				
3	0 00	2686503 012	214606 702	12 518262	1	48 7				
4	0 00	2651392 021	207497 886	12 777923	1	49 7				
5	0 00	2818743 727	225778 185	12 484571	1	48 6				
91	0 00	2878640 879	234438 081	12 278896	1	47 8				
92	0 00	2755468 758	225596 195	12 214163	1	47 5				
30	1 50	94111 99	227394 798	0 413870	1	1 57	4 7	1 52	1 3	5 1
63	1 50	126429 5	326318 409	0 387442	1	1 46	-2 7			
41	8 00	442829 095	230369 487	1 922256	1	7 44	-7 0	7 45	-6 9	0 1
74	8 00	525593 068	273232 124	1 923614	1	7 45	-6 9			
52	37 5	2148416 43	218467 963	9 834011	1	38 2	1 9	38 9	3 7	2 4
89	37 5	2388526 105	235375 843	10 147711	1	39 5	5 3			

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)
 AAR - Concentration Found is Greater than 50 0 (Highest Standard)

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 12
Serum, Concentration of Nicotine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
10	N/A	1 / Day 1 - 0 0333h	67685 306	207676 235	0 325917	1	1 23	20	05104620000721	AA97220-01 05104620000721 10 N/A Serum-1 1 / Day 1 - 0333h
10	N/A	1 / Day 1 - 0 0333h	101917 582	216730 567	0 470250	1	1 79	21	05104620000737	AA97220-01 05104620000737 10 N/A Serum-1 1 / Day 1 - 0333h
10	N/A	2 / Day 1 0h	73482 667	216088 548	0 340058	1	1 28	22	05104620000722	AA97220-01 05104620000722 10 N/A Serum-1 2 / Day 1 0h
10	N/A	2 / Day 1 0h	99545 328	228743 985	0 435182	1	1 65	23	05104620000738	AA97220-01 05104620000738 10 N/A Serum-1 2 / Day 1 0h
10	N/A	3 / Day 1 0 05h	72888 907	217907 148	0 334495	1	1 26	25	05104620000723	AA97220-01 05104620000723 10 N/A Serum-1 3 / Day 1 05h
10	N/A	3 / Day 1 0 05h	106702 295	229647 555	0 464635	1	1 77	24	05104620000739	AA97220-01 05104620000739 10 N/A Serum-1 3 / Day 1 05h
10	N/A	4 / Day 1 0 0833h	80655 175	214684 705	0 375691	1	1 42	27	05104620000724	AA97220-01 05104620000724 10 N/A Serum-1 4 / Day 1 0833h
10	N/A	4 / Day 1 0 0833h	108139 092	219227 877	0 493273	1	1 88	26	05104620000740	AA97220-01 05104620000740 10 N/A Serum-1 4 / Day 1 0833h
10	N/A	5 / Day 1 0 125h	101739 182	238425 039	0 426713	1	1 62	28	05104620000725	AA97220-01 05104620000725 10 N/A Serum-1 5 / Day 1 125h
10	N/A	5 / Day 1 0 125h	131791 687	228189 612	0 577553	1	2 20	29	05104620000741	AA97220-01 05104620000741 10 N/A Serum-1 5 / Day 1 125h
10	N/A	6 / Day 1 0 1667h	123299 965	235254 63	0 524113	1	2 00	32	05104620000726	AA97220-01 05104620000726 10 N/A Serum-1 6 / Day 1 1667h
10	N/A	6 / Day 1 0 1667h	150849 915	229819 61	0 656384	1	2 51	31	05104620000742	AA97220-01 05104620000742 10 N/A Serum-1 6 / Day 1 1667h
10	N/A	7 / Day 1 0 25h	150013 535	232792 218	0 644410	1	2 47	33	05104620000727	AA97220-01 05104620000727 10 N/A Serum-1 7 / Day 1 25h
10	N/A	7 / Day 1 0 25h	148714 141	228285 34	0 651440	1	2 49	34	05104620000743	AA97220-01 05104620000743 10 N/A Serum-1 7 / Day 1 25h
10	N/A	8 / Day 1 0 333h	223028 252	231797 62	0 962168	1	3 70	35	05104620000728	AA97220-01 05104620000728 10 N/A Serum-1 8 / Day 1 333h
10	N/A	8 / Day 1 0 333h	203033 123	236627 597	0 858028	1	3 30	36	05104620000744	AA97220-01 05104620000744 10 N/A Serum-1 8 / Day 1 333h
10	N/A	9 / Day 1 0 5h	289593 887	226658 753	1 277665	1	4 93	38	05104620000729	AA97220-01 05104620000729 10 N/A Serum-1 9 / Day 1 5h
10	N/A	9 / Day 1 0 5h	220580 178	226513 192	0 973807	1	3 75	37	05104620000745	AA97220-01 05104620000745 10 N/A Serum-1 9 / Day 1 5h
10	N/A	10 / Day 1 0 75h	227620 395	225674 343	1 008623	1	3 88	40	05104620000730	AA97220-01 05104620000730 10 N/A Serum-1 10 / Day 1 75h
10	N/A	10 / Day 1 0 75h	245730 929	227329 137	1 080948	1	4 16	39	05104620000746	AA97220-01 05104620000746 10 N/A Serum-1 10 / Day 1 75h
10	N/A	11 / Day 1 1h	198184 258	226693 941	0 874237	1	3 36	42	05104620000731	AA97220-01 05104620000731 10 N/A Serum-1 11 / Day 1 1h
10	N/A	11 / Day 1 1h	228882 273	229944 553	0 995380	1	3 83	43	05104620000747	AA97220-01 05104620000747 10 N/A Serum-1 11 / Day 1 1h
10	N/A	12 / Day 1 1 25h	172385 053	229475 678	0 751213	1	2 88	44	05104620000732	AA97220-01 05104620000732 10 N/A Serum-1 12 / Day 1 1 25h
10	N/A	12 / Day 1 1 25h	206505 735	231266 553	0 892934	1	3 43	45	05104620000748	AA97220-01 05104620000748 10 N/A Serum-1 12 / Day 1 1 25h
10	N/A	13 / Day 1 1 5h	152227 44	229403 963	0 663578	1	2 54	47	05104620000733	AA97220-01 05104620000733 10 N/A Serum-1 13 / Day 1 1 5h
10	N/A	13 / Day 1 1 5h	185722 33	230344 913	0 806279	1	3 10	46	05104620000749	AA97220-01 05104620000749 10 N/A Serum-1 13 / Day 1 1 5h
10	N/A	14 / Day 1 2h	113781 607	215265 66	0 528564	1	2 01	49	05104620000734	AA97220-01 05104620000734 10 N/A Serum-1 14 / Day 1 2h
10	N/A	14 / Day 1 2h	154037 38	226972 467	0 678661	1	2 60	48	05104620000750	AA97220-01 05104620000750 10 N/A Serum-1 14 / Day 1 2h
10	N/A	15 / Day 1 2 5h	99603 249	233404 16	0 426742	1	1 62	51	05104620000735	AA97220-01 05104620000735 10 N/A Serum-1 15 / Day 1 2 5h
10	N/A	15 / Day 1 2 5h	128148 683	226527 6	0 565709	1	2 16	50	05104620000751	AA97220-01 05104620000751 10 N/A Serum-1 15 / Day 1 2 5h
10	N/A	16 / Day 1 3h	95142 316	218268 23	0 435896	1	1 65	53	05104620000736	AA97220-01 05104620000736 10 N/A Serum-1 16 / Day 1 3h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
10	N/A	16 / Day 1 3h	109395 392	226069 938	0 483901	1	1 84	54	05104620000752	AA97220-01 05104620000752 10 N/A Serum-1 16 / Day 1 3h
11	N/A	1 / Day 1 - 0 0333h	46275 337	238693 113	0 193870	1	0 711	55	05104620000849	AA97220-01 05104620000849 11 N/A Serum-1 1 / Day 1 - 0333h
11	N/A	1 / Day 1 - 0 0333h	54780 148	212868 7	0 257342	1	0 958	56	05104620000865	AA97220-01 05104620000865 11 N/A Serum-1 1 / Day 1 - 0333h
11	N/A	2 / Day 1 0h	39013 598	230120 635	0 169535	1	0 616	58	05104620000850	AA97220-01 05104620000850 11 N/A Serum-1 2 / Day 1 0h
11	N/A	2 / Day 1 0h	56029 537	210570 51	0 266084	1	0 992	57	05104620000866	AA97220-01 05104620000866 11 N/A Serum-1 2 / Day 1 0h
11	N/A	3 / Day 1 0 05h	39107 927	231936 898	0 168615	1	0 613	59	05104620000851	AA97220-01 05104620000851 11 N/A Serum-1 3 / Day 1 05h
11	N/A	3 / Day 1 0 05h	1260941 273	257226 914	4 902058	1	19 0	60	05104620000867	AA97220-01 05104620000867 11 N/A Serum-1 3 / Day 1 05h
11	N/A	4 / Day 1 0 0833h	61714 536	341185 242	0 180883	1	0 660	62	05104620000852	AA97220-01 05104620000852 11 N/A Serum-1 4 / Day 1 0833h
11	N/A	4 / Day 1 0 0833h	2049601 174	257724 52	7 952682	1	30 9	61	05104620000868	AA97220-01 05104620000868 11 N/A Serum-1 4 / Day 1 0833h
11	N/A	5 / Day 1 0 125h	52985 137	279167 798	0 189797	1	0 695	65	05104620000853	AA97220-01 05104620000853 11 N/A Serum-1 5 / Day 1 125h
11	N/A	5 / Day 1 0 125h	1477639 354	292618 454	5 049713	1	19 6	64	05104620000869	AA97220-01 05104620000869 11 N/A Serum-1 5 / Day 1 125h
11	N/A	6 / Day 1 0 1667h	54867 744	237016 198	0 231494	1	0 857	67	05104620000854	AA97220-01 05104620000854 11 N/A Serum-1 6 / Day 1 1667h
11	N/A	6 / Day 1 0 1667h	931364 647	247001 207	3 770689	1	14 6	66	05104620000870	AA97220-01 05104620000870 11 N/A Serum-1 6 / Day 1 1667h
11	N/A	7 / Day 1 0 25h	54749 75	239977 43	0 228145	1	0 844	68	05104620000855	AA97220-01 05104620000855 11 N/A Serum-1 7 / Day 1 25h
11	N/A	7 / Day 1 0 25h	712127 65	238861 128	2 981346	1	11 6	69	05104620000871	AA97220-01 05104620000871 11 N/A Serum-1 7 / Day 1 25h
11	N/A	8 / Day 1 0 333h	58976 65	229475 845	0 257006	1	0 957	71	05104620000856	AA97220-01 05104620000856 11 N/A Serum-1 8 / Day 1 333h
11	N/A	8 / Day 1 0 333h	554826 722	238595 447	2 325387	1	9 01	70	05104620000872	AA97220-01 05104620000872 11 N/A Serum-1 8 / Day 1 333h
11	N/A	9 / Day 1 0 5h	80709 467	241753 415	0 333850	1	1 26	73	05104620000857	AA97220-01 05104620000857 11 N/A Serum-1 9 / Day 1 5h
11	N/A	9 / Day 1 0 5h	512803 517	264035 063	1 942180	1	7 52	72	05104620000873	AA97220-01 05104620000873 11 N/A Serum-1 9 / Day 1 5h
11	N/A	10 / Day 1 0 75h	105008 343	261312 418	0 401850	1	1 52	76	05104620000858	AA97220-01 05104620000858 11 N/A Serum-1 10 / Day 1 75h
11	N/A	10 / Day 1 0 75h	350828 827	256555 918	1 367456	1	5 28	75	05104620000874	AA97220-01 05104620000874 11 N/A Serum-1 10 / Day 1 75h
11	N/A	11 / Day 1 1h	127953 405	275599 713	0 464273	1	1 76	77	05104620000859	AA97220-01 05104620000859 11 N/A Serum-1 11 / Day 1 1h
11	N/A	11 / Day 1 1h	279684 652	250269 798	1 117533	1	4 31	78	05104620000875	AA97220-01 05104620000875 11 N/A Serum-1 11 / Day 1 1h
11	N/A	12 / Day 1 1 25h	111899 428	268494 532	0 416766	1	1 58	79	05104620000860	AA97220-01 05104620000860 11 N/A Serum-1 12 / Day 1 1 25h
11	N/A	12 / Day 1 1 25h	335096 518	270022 17	1 240996	1	4 79	80	05104620000876	AA97220-01 05104620000876 11 N/A Serum-1 12 / Day 1 1 25h
11	N/A	13 / Day 1 1 5h	131300 265	262469 388	0 500250	1	1 90	81	05104620000861	AA97220-01 05104620000861 11 N/A Serum-1 13 / Day 1 1 5h
11	N/A	13 / Day 1 1 5h	272380 503	271498 677	1 003248	1	3 86	82	05104620000877	AA97220-01 05104620000877 11 N/A Serum-1 13 / Day 1 1 5h
11	N/A	14 / Day 1 2h	97729 062	272604 96	0 358501	1	1 35	84	05104620000862	AA97220-01 05104620000862 11 N/A Serum-1 14 / Day 1 2h
11	N/A	14 / Day 1 2h	250847 738	283318 845	0 885390	1	3 40	83	05104620000878	AA97220-01 05104620000878 11 N/A Serum-1 14 / Day 1 2h
11	N/A	15 / Day 1 2 5h	79926 37	259923 412	0 307500	1	1 15	86	05104620000863	AA97220-01 05104620000863 11 N/A Serum-1 15 / Day 1 2 5h
11	N/A	15 / Day 1 2 5h	180402 892	278419 24	0 647954	1	2 48	85	05104620000879	AA97220-01 05104620000879 11 N/A Serum-1 15 / Day 1 2 5h
11	N/A	16 / Day 1 3h	73485 24	264196 901	0 278146	1	1 04	87	05104620000864	AA97220-01 05104620000864 11 N/A Serum-1 16 / Day 1 3h
11	N/A	16 / Day 1 3h	177924 487	277996 68	0 640024	1	2 45	88	05104620000880	AA97220-01 05104620000880 11 N/A Serum-1 16 / Day 1 3h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0.500 (Lowest Standard)

AAR - Concentration Found is Greater than 50.0 (Highest Standard)

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 13
 Serum, Concentration of Nicotine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		3947 305	391266 063	0 010089	0 00488		0 00119	438 7
9	0 00		3521 17	424841 797	0 008288	-0 00250			
10	0 500	4 00000	56396 958	427602 761	0 131891	0 504	0 8		
11	1 00	1 00000	93958 709	379427 783	0 247633	0 978	-2 2		
12	2 00	0 250000	211142 078	415293 54	0 508416	2 05	2 5		
13	4 00	0 0625000	416427 082	439760 963	0 946940	3 84	-4 0		
14	8 00	0 0156250	881757 869	436825 662	2 018558	8 23	2 9		
15	10 0	0 0100000	927690 728	383485 222	2 419104	9 88	-1 2		
16	20 0	0 00250000	2010530 059	392411 765	5 123521	21 0	5 0		
17	40 0	0 000625000	3928991 259	407131 289	9 650428	39 5	-1 3		
18	50 0	0 000400000	5564411 018	466292 265	11 933312	48 9	-2 2		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:
 Slope = 0 244052401
 Intercept = 0 00889914748
 R-Squared = 0 9989

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)
 AAR - Concentration Found is Greater than 50 0 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 13
 Serum, Concentration of Nicotine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	4876319 208	402916 758	12 102548	1	49 6		49 1		2 9
2	0 00	4653861 492	394897 5	11 784986	1	48 3				
3	0 00	4751669 762	378988 635	12 537763	1	51 3				
4	0 00	5107334 444	413418 643	12 353905	1	50 6				
5	0 00	4750070 614	402540 124	11 800241	1	48 3				
91	0 00	7188329 649	622001 929	11 556764	1	47 3				
92	0 00	7147720 636	604963 501	11 815127	1	48 4				
30	1 50	147962 818	436175 863	0 339227	1	1 35	-10 0	1 43	-4 7	7 9
63	1 50	166032 84	440950 818	0 376534	1	1 51	0 7			
41	8 00	748674 36	384862 9	1 945301	1	7 93	-0 9	7 92	-1 0	0 3
74	8 00	794832 268	410259 119	1 937391	1	7 90	-1 3			
52	37 5	3834970 166	416731 595	9 202494	1	37 7	0 5	37 2	-0 8	1 9
89	37 5	4812349 56	536198 228	8 974945	1	36 7	-2 1			

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)
 AAR - Concentration Found is Greater than 50 0 (Highest Standard)

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 13
Serum, Concentration of Nicotine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
11	N/A	1 / Day 1 - 0 0333h	78119 867	404021 542	0 193356	1	0 756	20	05104620000801	AA97220-01 05104620000801 11 N/A Serum-1 1 / Day 1 - 0333h
11	N/A	1 / Day 1 - 0 0333h	98788 574	438444 747	0 225316	1	0 887	21	05104620000817	AA97220-01 05104620000817 11 N/A Serum-1 1 / Day 1 - 0333h
11	N/A	1 / Day 1 - 0 0333h	83108 157	406743 487	0 204326	1	0 801	22	05104620000833	AA97220-01 05104620000833 11 N/A Serum-1 1 / Day 1 - 0333h
11	N/A	2 / Day 1 0h	66359 575	367801 76	0 180422	1	0 703	25	05104620000802	AA97220-01 05104620000802 11 N/A Serum-1 2 / Day 1 0h
11	N/A	2 / Day 1 0h	93924 602	397478 607	0 236301	1	0 932	23	05104620000818	AA97220-01 05104620000818 11 N/A Serum-1 2 / Day 1 0h
11	N/A	2 / Day 1 0h	84440 08	382548 97	0 220730	1	0 868	24	05104620000834	AA97220-01 05104620000834 11 N/A Serum-1 2 / Day 1 0h
11	N/A	3 / Day 1 0 05h	86014 443	446183 524	0 192778	1	0 753	28	05104620000803	AA97220-01 05104620000803 11 N/A Serum-1 3 / Day 1 05h
11	N/A	3 / Day 1 0 05h	99224 422	422831 55	0 234667	1	0 925	27	05104620000819	AA97220-01 05104620000819 11 N/A Serum-1 3 / Day 1 05h
11	N/A	3 / Day 1 0 05h	119368 792	395913 752	0 301502	1	1 20	26	05104620000835	AA97220-01 05104620000835 11 N/A Serum-1 3 / Day 1 05h
11	N/A	4 / Day 1 0 0833h	84634 54	370159 504	0 228643	1	0 900	32	05104620000804	AA97220-01 05104620000804 11 N/A Serum-1 4 / Day 1 0833h
11	N/A	4 / Day 1 0 0833h	99591 831	388388 958	0 256423	1	1 01	31	05104620000820	AA97220-01 05104620000820 11 N/A Serum-1 4 / Day 1 0833h
11	N/A	4 / Day 1 0 0833h	177606 058	432793 89	0 410371	1	1 65	29	05104620000836	AA97220-01 05104620000836 11 N/A Serum-1 4 / Day 1 0833h
11	N/A	5 / Day 1 0 125h	82018 12	391384 992	0 209559	1	0 822	34	05104620000805	AA97220-01 05104620000805 11 N/A Serum-1 5 / Day 1 125h
11	N/A	5 / Day 1 0 125h	103892 52	331690 097	0 313222	1	1 25	35	05104620000821	AA97220-01 05104620000821 11 N/A Serum-1 5 / Day 1 125h
11	N/A	5 / Day 1 0 125h	160126 046	403622 747	0 396722	1	1 59	33	05104620000837	AA97220-01 05104620000837 11 N/A Serum-1 5 / Day 1 125h
11	N/A	6 / Day 1 0 1667h	110631 035	410558 164	0 269465	1	1 07	36	05104620000806	AA97220-01 05104620000806 11 N/A Serum-1 6 / Day 1 1667h
11	N/A	6 / Day 1 0 1667h	141780 59	385703 703	0 367589	1	1 47	38	05104620000822	AA97220-01 05104620000822 11 N/A Serum-1 6 / Day 1 1667h
11	N/A	6 / Day 1 0 1667h	157334 129	378025 304	0 416200	1	1 67	37	05104620000838	AA97220-01 05104620000838 11 N/A Serum-1 6 / Day 1 1667h
11	N/A	7 / Day 1 0 25h	118866 48	376209 675	0 315958	1	1 26	39	05104620000807	AA97220-01 05104620000807 11 N/A Serum-1 7 / Day 1 25h
11	N/A	7 / Day 1 0 25h	178145 586	407810 758	0 436834	1	1 75	42	05104620000823	AA97220-01 05104620000823 11 N/A Serum-1 7 / Day 1 25h
11	N/A	7 / Day 1 0 25h	182502 556	374048 128	0 487912	1	1 96	40	05104620000839	AA97220-01 05104620000839 11 N/A Serum-1 7 / Day 1 25h
11	N/A	8 / Day 1 0 333h	142264 386	383320 88	0 371137	1	1 48	44	05104620000808	AA97220-01 05104620000808 11 N/A Serum-1 8 / Day 1 333h
11	N/A	8 / Day 1 0 333h	172034 678	399668 727	0 430443	1	1 73	43	05104620000824	AA97220-01 05104620000824 11 N/A Serum-1 8 / Day 1 333h
11	N/A	8 / Day 1 0 333h	198165 603	373745 62	0 530215	1	2 14	45	05104620000840	AA97220-01 05104620000840 11 N/A Serum-1 8 / Day 1 333h
11	N/A	9 / Day 1 0 5h	146834 012	389930 489	0 376565	1	1 51	46	05104620000809	AA97220-01 05104620000809 11 N/A Serum-1 9 / Day 1 5h
11	N/A	9 / Day 1 0 5h	179894 141	425059 592	0 423221	1	1 70	47	05104620000825	AA97220-01 05104620000825 11 N/A Serum-1 9 / Day 1 5h
11	N/A	9 / Day 1 0 5h	160754 835	344958 253	0 466012	1	1 87	48	05104620000841	AA97220-01 05104620000841 11 N/A Serum-1 9 / Day 1 5h
11	N/A	10 / Day 1 0 75h	132707 897	400061 767	0 331719	1	1 32	49	05104620000810	AA97220-01 05104620000810 11 N/A Serum-1 10 / Day 1 75h
11	N/A	10 / Day 1 0 75h	203381 181	348802 033	0 583085	1	2 35	51	05104620000826	AA97220-01 05104620000826 11 N/A Serum-1 10 / Day 1 75h
11	N/A	10 / Day 1 0 75h	176251 548	409351 388	0 430563	1	1 73	50	05104620000842	AA97220-01 05104620000842 11 N/A Serum-1 10 / Day 1 75h
11	N/A	11 / Day 1 1h	232089 211	492294 247	0 471444	1	1 90	54	05104620000811	AA97220-01 05104620000811 11 N/A Serum-1 11 / Day 1 1h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
11	N/A	11 / Day 1 1h	156710 914	332531 902	0 471266	1	1 89	55	05104620000827	AA97220-01 05104620000827 11 N/A Serum-1 11 / Day 1 1h
11	N/A	11 / Day 1 1h	141184 193	379992 74	0 371544	1	1 49	53	05104620000843	AA97220-01 05104620000843 11 N/A Serum-1 11 / Day 1 1h
11	N/A	12 / Day 1 1 25h	190994 812	384106 278	0 497245	1	2 00	58	05104620000812	AA97220-01 05104620000812 11 N/A Serum-1 12 / Day 1 1 25h
11	N/A	12 / Day 1 1 25h	188267 36	401330 063	0 469109	1	1 89	57	05104620000828	AA97220-01 05104620000828 11 N/A Serum-1 12 / Day 1 1 25h
11	N/A	12 / Day 1 1 25h	150887 287	410887 185	0 367223	1	1 47	56	05104620000844	AA97220-01 05104620000844 11 N/A Serum-1 12 / Day 1 1 25h
11	N/A	13 / Day 1 1 5h	201245 044	421810 088	0 477099	1	1 92	61	05104620000813	AA97220-01 05104620000813 11 N/A Serum-1 13 / Day 1 1 5h
11	N/A	13 / Day 1 1 5h	181488 75	401964 096	0 451505	1	1 81	60	05104620000829	AA97220-01 05104620000829 11 N/A Serum-1 13 / Day 1 1 5h
11	N/A	13 / Day 1 1 5h	144459 124	395038 199	0 365684	1	1 46	59	05104620000845	AA97220-01 05104620000845 11 N/A Serum-1 13 / Day 1 1 5h
11	N/A	14 / Day 1 2h	143836 264	390969 728	0 367896	1	1 47	65	05104620000814	AA97220-01 05104620000814 11 N/A Serum-1 14 / Day 1 2h
11	N/A	14 / Day 1 2h	153047 932	409622 415	0 373632	1	1 49	64	05104620000830	AA97220-01 05104620000830 11 N/A Serum-1 14 / Day 1 2h
11	N/A	14 / Day 1 2h	150072 118	488598 86	0 307148	1	1 22	62	05104620000846	AA97220-01 05104620000846 11 N/A Serum-1 14 / Day 1 2h
11	N/A	15 / Day 1 2 5h	140228 224	433348 742	0 323592	1	1 29	68	05104620000815	AA97220-01 05104620000815 11 N/A Serum-1 15 / Day 1 2 5h
11	N/A	15 / Day 1 2 5h	141810 599	435515 748	0 325615	1	1 30	66	05104620000831	AA97220-01 05104620000831 11 N/A Serum-1 15 / Day 1 2 5h
11	N/A	15 / Day 1 2 5h	140050 301	481597 805	0 290803	1	1 16	67	05104620000847	AA97220-01 05104620000847 11 N/A Serum-1 15 / Day 1 2 5h
11	N/A	16 / Day 1 3h	115590 687	432269 914	0 267404	1	1 06	71	05104620000816	AA97220-01 05104620000816 11 N/A Serum-1 16 / Day 1 3h
11	N/A	16 / Day 1 3h	144581 83	460863 048	0 313720	1	1 25	69	05104620000832	AA97220-01 05104620000832 11 N/A Serum-1 16 / Day 1 3h
11	N/A	16 / Day 1 3h	123292 906	483181 93	0 255169	1	1 01	70	05104620000848	AA97220-01 05104620000848 11 N/A Serum-1 16 / Day 1 3h
12	N/A	1 / Day 1 - 0 0333h	655188 606	576037 937	1 137405	1	4 62	72	05104620000945	AA97220-01 05104620000945 12 N/A Serum-1 1 / Day 1 - 0333h
12	N/A	2 / Day 1 0h	480422 488	389896 735	1 232179	1	5 01	73	05104620000946	AA97220-01 05104620000946 12 N/A Serum-1 2 / Day 1 0h
12	N/A	3 / Day 1 0 05h	4675934 175	508706 205	9 191817	1	37 6	75	05104620000947	AA97220-01 05104620000947 12 N/A Serum-1 3 / Day 1 05h
12	N/A	4 / Day 1 0 0833h	3799631 219	396098 362	9 592646	1	39 3	76	05104620000948	AA97220-01 05104620000948 12 N/A Serum-1 4 / Day 1 0833h
12	N/A	5 / Day 1 0 125h	3420152 321	397477 542	8 604643	1	35 2	77	05104620000949	AA97220-01 05104620000949 12 N/A Serum-1 5 / Day 1 125h
12	N/A	6 / Day 1 0 1667h	3574616 462	433835 304	8 239570	1	33 7	78	05104620000950	AA97220-01 05104620000950 12 N/A Serum-1 6 / Day 1 1667h
12	N/A	7 / Day 1 0 25h	3039066 847	417037 338	7 287278	1	29 8	79	05104620000951	AA97220-01 05104620000951 12 N/A Serum-1 7 / Day 1 25h
12	N/A	8 / Day 1 0 333h	2630326 209	415201 812	6 335055	1	25 9	80	05104620000952	AA97220-01 05104620000952 12 N/A Serum-1 8 / Day 1 333h
12	N/A	9 / Day 1 0 5h	3066887 182	593406 644	5 168272	1	21 1	81	05104620000953	AA97220-01 05104620000953 12 N/A Serum-1 9 / Day 1 5h
12	N/A	10 / Day 1 0 75h	2263904 862	509716 572	4 441497	1	18 2	82	05104620000954	AA97220-01 05104620000954 12 N/A Serum-1 10 / Day 1 75h
12	N/A	11 / Day 1 1h	1917183 967	525938 045	3 645266	1	14 9	83	05104620000955	AA97220-01 05104620000955 12 N/A Serum-1 11 / Day 1 1h
12	N/A	12 / Day 1 1 25h	1789361 588	570253 254	3 137837	1	12 8	84	05104620000956	AA97220-01 05104620000956 12 N/A Serum-1 12 / Day 1 1 25h
12	N/A	13 / Day 1 1 5h	1539004 571	555097 44	2 772494	1	11 3	85	05104620000957	AA97220-01 05104620000957 12 N/A Serum-1 13 / Day 1 1 5h
12	N/A	14 / Day 1 2h	1173882 472	536020 27	2 189996	1	8 94	86	05104620000958	AA97220-01 05104620000958 12 N/A Serum-1 14 / Day 1 2h
12	N/A	15 / Day 1 2 5h	1068870 734	531414 618	2 011369	1	8 21	87	05104620000959	AA97220-01 05104620000959 12 N/A Serum-1 15 / Day 1 2 5h
12	N/A	16 / Day 1 3h	1043929 914	549372 753	1 900221	1	7 75	88	05104620000960	AA97220-01 05104620000960 12 N/A Serum-1 16 / Day 1 3h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0.500 (Lowest Standard)

AAR - Concentration Found is Greater than 50.0 (Highest Standard)

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 14
 Serum, Concentration of Nicotine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		7643 622	503077 068	0 015194	0 0275		0 0175	81 1
9	0 00		5130 144	501713 49	0 010225	0 00743			
10	0 500	4 00000	63178 589	481999 683	0 131076	0 495	-1 0		
11	1 00	1 00000	130692 38	515971 777	0 253294	0 988	-1 2		
12	2 00	0 250000	275136 317	512237 998	0 537126	2 13	6 5		
13	4 00	0 0625000	495020 117	486518 655	1 017474	4 07	1 8		
14	8 00	0 0156250	947422 598	491116 25	1 929121	7 75	-3 1		
15	10 0	0 0100000	1232306 245	500331 774	2 462978	9 90	-1 0		
16	20 0	0 00250000	2516311 563	498624 692	5 046504	20 3	1 5		
17	40 0	0 000625000	4932688 714	487390 522	10 120609	40 8	2 0		
18	50 0	0 000400000	5856062 423	499730 815	11 718434	47 2	-5 6		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:
 Slope = 0 247933629
 Intercept = 0 00838375105
 R-Squared = 0 9983

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)
 AAR - Concentration Found is Greater than 50 0 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 14
Serum, Concentration of Nicotine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	6798301 776	578299 065	11 755685	1	47 4		47 9		1 6
2	0 00	6705410 753	551849 234	12 150802	1	49 0				
3	0 00	6486927 072	542637 38	11 954442	1	48 2				
4	0 00	6500851 471	547758 604	11 868096	1	47 8				
5	0 00	6599568 458	570489 107	11 568264	1	46 6				
91	0 00	6535560 793	550707 951	11 867562	1	47 8				
92	0 00	6543663 088	547039 343	11 961961	1	48 2				
30	1 50	183427 626	525009 59	0 349380	1	1 38	-8 0	1 45	-3 3	6 3
63	1 50	193058 911	505147 623	0 382183	1	1 51	0 7			
41	8 00	999640 155	546660 07	1 828632	1	7 34	-8 3	7 38	-7 8	0 8
74	8 00	965047 178	521860 133	1 849245	1	7 42	-7 3			
52	37 5	4628550 941	493077 363	9 387068	1	37 8	0 8	37 6	0 3	0 9
89	37 5	4613525 678	498561 277	9 253678	1	37 3	-0 5			

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)
AAR - Concentration Found is Greater than 50 0 (Highest Standard)

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 14
Serum, Concentration of Nicotine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
12	N/A	1 / Day 1 - 0 0333h	2003932 276	500825 222	4 001261	1	16 1	22	05104620000881	AA97220-01 05104620000881 12 N/A Serum-1 1 / Day 1 - 0333h
12	N/A	1 / Day 1 - 0 0333h	1421137 826	480137 238	2 959858	1	11 9	23	05104620000897	AA97220-01 05104620000897 12 N/A Serum-1 1 / Day 1 - 0333h
12	N/A	1 / Day 1 - 0 0333h	791737 706	485199 102	1 631779	1	6 55	20	05104620000913	AA97220-01 05104620000913 12 N/A Serum-1 1 / Day 1 - 0333h
12	N/A	1 / Day 1 - 0 0333h	516076 573	492892 713	1 047036	1	4 19	21	05104620000929	AA97220-01 05104620000929 12 N/A Serum-1 1 / Day 1 - 0333h
12	N/A	2 / Day 1 0h	2236766 102	514446 8	4 347906	1	17 5	26	05104620000882	AA97220-01 05104620000882 12 N/A Serum-1 2 / Day 1 0h
12	N/A	2 / Day 1 0h	1423791 912	467733 881	3 044021	1	12 2	25	05104620000898	AA97220-01 05104620000898 12 N/A Serum-1 2 / Day 1 0h
12	N/A	2 / Day 1 0h	823378 366	478080 368	1 722259	1	6 91	24	05104620000914	AA97220-01 05104620000914 12 N/A Serum-1 2 / Day 1 0h
12	N/A	2 / Day 1 0h	467838 895	493432 51	0 948131	1	3 79	27	05104620000930	AA97220-01 05104620000930 12 N/A Serum-1 2 / Day 1 0h
12	N/A	3 / Day 1 0 05h	2105057 401	507866 309	4 144905	1	16 7	28	05104620000883	AA97220-01 05104620000883 12 N/A Serum-1 3 / Day 1 05h
12	N/A	3 / Day 1 0 05h	1428461 073	510983 948	2 795511	1	11 2	31	05104620000899	AA97220-01 05104620000899 12 N/A Serum-1 3 / Day 1 05h
12	N/A	3 / Day 1 0 05h	903875 943	527987 3	1 711927	1	6 87	32	05104620000915	AA97220-01 05104620000915 12 N/A Serum-1 3 / Day 1 05h
12	N/A	3 / Day 1 0 05h	398355 11	516170 13	0 771752	1	3 08	29	05104620000931	AA97220-01 05104620000931 12 N/A Serum-1 3 / Day 1 05h
12	N/A	4 / Day 1 0 0833h	2075772 521	516049 998	4 022425	1	16 2	36	05104620000884	AA97220-01 05104620000884 12 N/A Serum-1 4 / Day 1 0833h
12	N/A	4 / Day 1 0 0833h	1368779 896	514570 842	2 660042	1	10 7	34	05104620000900	AA97220-01 05104620000900 12 N/A Serum-1 4 / Day 1 0833h
12	N/A	4 / Day 1 0 0833h	918427 069	526161 601	1 745523	1	7 01	35	05104620000916	AA97220-01 05104620000916 12 N/A Serum-1 4 / Day 1 0833h
12	N/A	4 / Day 1 0 0833h	443825 416	520697 69	0 852367	1	3 40	33	05104620000932	AA97220-01 05104620000932 12 N/A Serum-1 4 / Day 1 0833h
12	N/A	5 / Day 1 0 125h	2054818 411	504759 653	4 070885	1	16 4	37	05104620000885	AA97220-01 05104620000885 12 N/A Serum-1 5 / Day 1 125h
12	N/A	5 / Day 1 0 125h	1457677 449	501429 798	2 907042	1	11 7	38	05104620000901	AA97220-01 05104620000901 12 N/A Serum-1 5 / Day 1 125h
12	N/A	5 / Day 1 0 125h	1021781 483	508008 058	2 011349	1	8 08	39	05104620000917	AA97220-01 05104620000917 12 N/A Serum-1 5 / Day 1 125h
12	N/A	5 / Day 1 0 125h	519163 172	521582 27	0 995362	1	3 98	40	05104620000933	AA97220-01 05104620000933 12 N/A Serum-1 5 / Day 1 125h
12	N/A	6 / Day 1 0 1667h	2272722 458	521175 99	4 360758	1	17 6	42	05104620000886	AA97220-01 05104620000886 12 N/A Serum-1 6 / Day 1 1667h
12	N/A	6 / Day 1 0 1667h	1459615 806	523019 753	2 790747	1	11 2	44	05104620000902	AA97220-01 05104620000902 12 N/A Serum-1 6 / Day 1 1667h
12	N/A	6 / Day 1 0 1667h	1040423 887	515513 89	2 018227	1	8 11	45	05104620000918	AA97220-01 05104620000918 12 N/A Serum-1 6 / Day 1 1667h
12	N/A	6 / Day 1 0 1667h	561223 893	500696 82	1 120886	1	4 49	43	05104620000934	AA97220-01 05104620000934 12 N/A Serum-1 6 / Day 1 1667h
12	N/A	7 / Day 1 0 25h	2355045 373	532102 029	4 425928	1	17 8	49	05104620000887	AA97220-01 05104620000887 12 N/A Serum-1 7 / Day 1 25h
12	N/A	7 / Day 1 0 25h	1448990 007	497233 23	2 914105	1	11 7	48	05104620000903	AA97220-01 05104620000903 12 N/A Serum-1 7 / Day 1 25h
12	N/A	7 / Day 1 0 25h	1023344 762	498268 332	2 053803	1	8 25	47	05104620000919	AA97220-01 05104620000919 12 N/A Serum-1 7 / Day 1 25h
12	N/A	7 / Day 1 0 25h	605901 26	499126 428	1 213923	1	4 86	46	05104620000935	AA97220-01 05104620000935 12 N/A Serum-1 7 / Day 1 25h
12	N/A	8 / Day 1 0 333h	2272095 091	504476 676	4 503865	1	18 1	51	05104620000888	AA97220-01 05104620000888 12 N/A Serum-1 8 / Day 1 333h
12	N/A	8 / Day 1 0 333h	1414054 549	497710 002	2 841121	1	11 4	53	05104620000904	AA97220-01 05104620000904 12 N/A Serum-1 8 / Day 1 333h
12	N/A	8 / Day 1 0 333h	1140456 563	525264 71	2 171203	1	8 72	54	05104620000920	AA97220-01 05104620000920 12 N/A Serum-1 8 / Day 1 333h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
12	N/A	8 / Day 1 0 333h	658171 846	520826 29	1 263707	1	5 06	50	05104620000936	AA97220-01 05104620000936 12 N/A Serum-1 8 / Day 1 333h
12	N/A	9 / Day 1 0 5h	2324577 287	505964 338	4 594350	1	18 5	58	05104620000889	AA97220-01 05104620000889 12 N/A Serum-1 9 / Day 1 5h
12	N/A	9 / Day 1 0 5h	1348928 803	515879 87	2 614812	1	10 5	57	05104620000905	AA97220-01 05104620000905 12 N/A Serum-1 9 / Day 1 5h
12	N/A	9 / Day 1 0 5h	943862 19	510322 327	1 849541	1	7 43	56	05104620000921	AA97220-01 05104620000921 12 N/A Serum-1 9 / Day 1 5h
12	N/A	9 / Day 1 0 5h	674515 331	531422 67	1 269263	1	5 09	55	05104620000937	AA97220-01 05104620000937 12 N/A Serum-1 9 / Day 1 5h
12	N/A	10 / Day 1 0 75h	2376940 496	497203 625	4 780618	1	19 2	61	05104620000890	AA97220-01 05104620000890 12 N/A Serum-1 10 / Day 1 75h
12	N/A	10 / Day 1 0 75h	1344266 283	497421 574	2 702469	1	10 9	62	05104620000906	AA97220-01 05104620000906 12 N/A Serum-1 10 / Day 1 75h
12	N/A	10 / Day 1 0 75h	895998 103	495998 92	1 806452	1	7 25	60	05104620000922	AA97220-01 05104620000922 12 N/A Serum-1 10 / Day 1 75h
12	N/A	10 / Day 1 0 75h	713692 277	505355 442	1 412258	1	5 66	59	05104620000938	AA97220-01 05104620000938 12 N/A Serum-1 10 / Day 1 75h
12	N/A	11 / Day 1 1h	2125321 45	507003 763	4 191924	1	16 9	64	05104620000891	AA97220-01 05104620000891 12 N/A Serum-1 11 / Day 1 1h
12	N/A	11 / Day 1 1h	1209880 953	510151 368	2 371612	1	9 53	67	05104620000907	AA97220-01 05104620000907 12 N/A Serum-1 11 / Day 1 1h
12	N/A	11 / Day 1 1h	965431 822	505829 973	1 908609	1	7 66	66	05104620000923	AA97220-01 05104620000923 12 N/A Serum-1 11 / Day 1 1h
12	N/A	11 / Day 1 1h	530236 007	510242 152	1 039185	1	4 16	65	05104620000939	AA97220-01 05104620000939 12 N/A Serum-1 11 / Day 1 1h
12	N/A	12 / Day 1 1 25h	2070406 282	495948 36	4 174641	1	16 8	68	05104620000892	AA97220-01 05104620000892 12 N/A Serum-1 12 / Day 1 1 25h
12	N/A	12 / Day 1 1 25h	1081069 856	503955 092	2 145171	1	8 62	71	05104620000908	AA97220-01 05104620000908 12 N/A Serum-1 12 / Day 1 1 25h
12	N/A	12 / Day 1 1 25h	796797 002	504925 625	1 578048	1	6 33	70	05104620000924	AA97220-01 05104620000924 12 N/A Serum-1 12 / Day 1 1 25h
12	N/A	12 / Day 1 1 25h	474576 192	505538 795	0 938753	1	3 75	69	05104620000940	AA97220-01 05104620000940 12 N/A Serum-1 12 / Day 1 1 25h
12	N/A	13 / Day 1 1 5h	1595874 864	493560 191	3 233395	1	13 0	75	05104620000893	AA97220-01 05104620000893 12 N/A Serum-1 13 / Day 1 1 5h
12	N/A	13 / Day 1 1 5h	959470 946	493586 67	1 943875	1	7 81	73	05104620000909	AA97220-01 05104620000909 12 N/A Serum-1 13 / Day 1 1 5h
12	N/A	13 / Day 1 1 5h	889877 314	516454 057	1 723052	1	6 92	72	05104620000925	AA97220-01 05104620000925 12 N/A Serum-1 13 / Day 1 1 5h
12	N/A	13 / Day 1 1 5h	541361 112	519149 388	1 042785	1	4 17	76	05104620000941	AA97220-01 05104620000941 12 N/A Serum-1 13 / Day 1 1 5h
12	N/A	14 / Day 1 2h	1540712 646	518015 435	2 974260	1	12 0	78	05104620000894	AA97220-01 05104620000894 12 N/A Serum-1 14 / Day 1 2h
12	N/A	14 / Day 1 2h	817128 828	515062 205	1 586466	1	6 36	80	05104620000910	AA97220-01 05104620000910 12 N/A Serum-1 14 / Day 1 2h
12	N/A	14 / Day 1 2h	666880 268	494545 47	1 348471	1	5 41	79	05104620000926	AA97220-01 05104620000926 12 N/A Serum-1 14 / Day 1 2h
12	N/A	14 / Day 1 2h	515255 667	495459 807	1 039955	1	4 16	77	05104620000942	AA97220-01 05104620000942 12 N/A Serum-1 14 / Day 1 2h
12	N/A	15 / Day 1 2 5h	1184433 442	513385 004	2 307106	1	9 27	81	05104620000895	AA97220-01 05104620000895 12 N/A Serum-1 15 / Day 1 2 5h
12	N/A	15 / Day 1 2 5h	753247 396	519793 19	1 449129	1	5 81	84	05104620000911	AA97220-01 05104620000911 12 N/A Serum-1 15 / Day 1 2 5h
12	N/A	15 / Day 1 2 5h	605210 824	505268 642	1 197800	1	4 80	83	05104620000927	AA97220-01 05104620000927 12 N/A Serum-1 15 / Day 1 2 5h
12	N/A	15 / Day 1 2 5h	370534 877	516568 637	0 717300	1	2 86	82	05104620000943	AA97220-01 05104620000943 12 N/A Serum-1 15 / Day 1 2 5h
12	N/A	16 / Day 1 3h	1175519 607	511807 47	2 296800	1	9 23	86	05104620000896	AA97220-01 05104620000896 12 N/A Serum-1 16 / Day 1 3h
12	N/A	16 / Day 1 3h	651448 693	523779 313	1 243747	1	4 98	88	05104620000912	AA97220-01 05104620000912 12 N/A Serum-1 16 / Day 1 3h
12	N/A	16 / Day 1 3h	548309 294	534164 872	1 026480	1	4 11	87	05104620000928	AA97220-01 05104620000928 12 N/A Serum-1 16 / Day 1 3h
12	N/A	16 / Day 1 3h	332258 401	503269 182	0 660200	1	2 63	85	05104620000944	AA97220-01 05104620000944 12 N/A Serum-1 16 / Day 1 3h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0.500 (Lowest Standard)

AAR - Concentration Found is Greater than 50.0 (Highest Standard)

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 16
 Serum, Concentration of Nicotine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		1848 864	31832 79	0 058080	0 0363		0 0340	9 8
9	0 00		1747 981	31941 783	0 054724	0 0316			
10	0 500	4 00000	12377 007	32333 095	0 382797	0 485	-3 0		
11	1 00	1 00000	21304 018	26945 168	0 790643	1 05	5 0		
12	2 00	0 250000	40077 63	26031 083	1 539607	2 08	4 0		
13	4 00	0 0625000	72124 388	25889 882	2 785814	3 81	-4 8		
14	8 00	0 0156250	154560 005	27108 22	5 701592	7 83	-2 1		
15	10 0	0 0100000	189371 253	24570 553	7 707244	10 6	6 0		
16	20 0	0 00250000	367173 566	24948 477	14 717274	20 3	1 5		
17	40 0	0 000625000	780785 806	27027 298	28 888785	39 9	-0 3		
18	50 0	0 000400000	871456 291	25676 257	33 940161	46 9	-6 2		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:

Slope = 0 723699366

Intercept = 0 0318205540

R-Squared = 0 9974

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)

AAR - Concentration Found is Greater than 50 0 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 16
Serum, Concentration of Nicotine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	1061354 667	29833 543	35 575884	1	49 1		48 3		3 4
2	0 00	973369 125	26032 328	37 390783	1	51 6				
3	0 00	950119 538	27204 592	34 924969	1	48 2				
4	0 00	942042 739	27354 674	34 438091	1	47 5				
5	0 00	974207 944	28662 8	33 988583	1	46 9				
90	0 00	1490934 913	43430 897	34 328900	1	47 4				
91	0 00	1567659 504	45950 085	34 116575	1	47 1				
30	1 50	62476 708	61349 937	*1 018366	1	*1 36				
63	1 50	19916 512	17172 573	1 159786	1	1 56	4 0			
41	8 00	211470 723	38993 448	5 423237	1	7 45	-6 9	7 52	-6 0	1 2
74	8 00	125577 345	22755 199	5 518622	1	7 58	-5 3			
52	37 5	520877 411	19840 817	26 252821	1	36 2	-3 5			
88	37 5	1610985 275	62696 363	*25 695036	1	*35 5				

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)
AAR - Concentration Found is Greater than 50 0 (Highest Standard)

Reason for Deactivation of Sample

* UISR

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 16
Serum, Concentration of Nicotine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
13	N/A	1 / Day 1 - 0 0333h	17004 845	23325 039	0 729038	1	0 963	20	05104620000961	AA97220-01 05104620000961 13 N/A Serum-1 1 / Day 1 - 0333h
13	N/A	2 / Day 1 0h	18975 01	29604 5	0 640950	1	0 842	21	05104620000962	AA97220-01 05104620000962 13 N/A Serum-1 2 / Day 1 0h
13	N/A	3 / Day 1 0 05h	20846 577	29718 023	0 701479	1	0 925	22	05104620000963	AA97220-01 05104620000963 13 N/A Serum-1 3 / Day 1 05h
13	N/A	4 / Day 1 0 0833h	19761 028	26763 197	0 738366	1	0 976	23	05104620000964	AA97220-01 05104620000964 13 N/A Serum-1 4 / Day 1 0833h
13	N/A	5 / Day 1 0 125h	24197 305	29019 985	0 833815	1	1 11	24	05104620000965	AA97220-01 05104620000965 13 N/A Serum-1 5 / Day 1 125h
13	N/A	6 / Day 1 0 1667h	35364 475	33910 282	1 042884	1	1 40	25	05104620000966	AA97220-01 05104620000966 13 N/A Serum-1 6 / Day 1 1667h
13	N/A	7 / Day 1 0 25h	38669 028	31923 412	1 211306	1	1 63	26	05104620000967	AA97220-01 05104620000967 13 N/A Serum-1 7 / Day 1 25h
13	N/A	8 / Day 1 0 333h	54313 865	36057 345	1 506319	1	2 04	27	05104620000968	AA97220-01 05104620000968 13 N/A Serum-1 8 / Day 1 333h
13	N/A	9 / Day 1 0 5h	49032 175	33530 098	1 462333	1	1 98	28	05104620000969	AA97220-01 05104620000969 13 N/A Serum-1 9 / Day 1 5h
13	N/A	10 / Day 1 0 75h	79257 383	52226 674	1 517565	1	2 05	29	05104620000970	AA97220-01 05104620000970 13 N/A Serum-1 10 / Day 1 75h
13	N/A	11 / Day 1 1h	80556 3	65864 16	*1 223067	1	*1 65	31	05104620000971	AA97220-01 05104620000971 13 N/A Serum-1 11 / Day 1 1h
13	N/A	12 / Day 1 1 25h	24891 667	19386 597	1 283963	1	1 73	32	05104620000972	AA97220-01 05104620000972 13 N/A Serum-1 12 / Day 1 1 25h
13	N/A	13 / Day 1 1 5h	19393 673	16929 337	1 145566	1	1 54	33	05104620000973	AA97220-01 05104620000973 13 N/A Serum-1 13 / Day 1 1 5h
13	N/A	14 / Day 1 2h	19704 752	20797 732	0 947447	1	1 27	34	05104620000974	AA97220-01 05104620000974 13 N/A Serum-1 14 / Day 1 2h
13	N/A	15 / Day 1 2 5h	26160 217	27051 843	0 967040	1	1 29	35	05104620000975	AA97220-01 05104620000975 13 N/A Serum-1 15 / Day 1 2 5h
13	N/A	16 / Day 1 3h	22146 3	26921 343	0 822630	1	1 09	36	05104620000976	AA97220-01 05104620000976 13 N/A Serum-1 16 / Day 1 3h
14	N/A	1 / Day 1 - 0 0333h	16674 01	25599 26	0 651347	1	0 856	38	05104620001073	AA97220-01 05104620001073 14 N/A Serum-1 1 / Day 1 - 0333h
14	N/A	1 / Day 1 - 0 0333h	17372 453	29971 467	0 579633	1	0 757	39	05104620001089	AA97220-01 05104620001089 14 N/A Serum-1 1 / Day 1 - 0333h
14	N/A	1 / Day 1 - 0 0333h	25777 42	32065 833	0 803891	1	1 07	37	05104620001105	AA97220-01 05104620001105 14 N/A Serum-1 1 / Day 1 - 0333h
14	N/A	2 / Day 1 0h	27612 057	39413 517	0 700573	1	0 924	43	05104620001074	AA97220-01 05104620001074 14 N/A Serum-1 2 / Day 1 0h
14	N/A	2 / Day 1 0h	22424 782	38814 975	0 577735	1	0 754	40	05104620001090	AA97220-01 05104620001090 14 N/A Serum-1 2 / Day 1 0h
14	N/A	2 / Day 1 0h	28565 123	42547 347	0 671373	1	0 884	42	05104620001106	AA97220-01 05104620001106 14 N/A Serum-1 2 / Day 1 0h
14	N/A	3 / Day 1 0 05h	13953 277	20351 517	0 685614	1	0 903	46	05104620001075	AA97220-01 05104620001075 14 N/A Serum-1 3 / Day 1 05h
14	N/A	3 / Day 1 0 05h	32244 708	43361 324	0 743628	1	0 984	44	05104620001091	AA97220-01 05104620001091 14 N/A Serum-1 3 / Day 1 05h
14	N/A	3 / Day 1 0 05h	122004 996	48053 637	2 538934	1	3 46	45	05104620001107	AA97220-01 05104620001107 14 N/A Serum-1 3 / Day 1 05h
14	N/A	4 / Day 1 0 0833h	21084 343	19323 767	1 091109	1	1 46	48	05104620001076	AA97220-01 05104620001076 14 N/A Serum-1 4 / Day 1 0833h
14	N/A	4 / Day 1 0 0833h	22933 86	21028 582	1 090604	1	1 46	49	05104620001092	AA97220-01 05104620001092 14 N/A Serum-1 4 / Day 1 0833h
14	N/A	4 / Day 1 0 0833h	83182 695	18573 748	4 478509	1	6 14	47	05104620001108	AA97220-01 05104620001108 14 N/A Serum-1 4 / Day 1 0833h
14	N/A	5 / Day 1 0 125h	31129 837	20843 793	1 493482	1	2 02	53	05104620001077	AA97220-01 05104620001077 14 N/A Serum-1 5 / Day 1 125h
14	N/A	5 / Day 1 0 125h	27807 338	20722 692	1 341879	1	1 81	50	05104620001093	AA97220-01 05104620001093 14 N/A Serum-1 5 / Day 1 125h
14	N/A	5 / Day 1 0 125h	131423 976	22740 642	5 779255	1	7 94	51	05104620001109	AA97220-01 05104620001109 14 N/A Serum-1 5 / Day 1 125h
14	N/A	6 / Day 1 0 1667h	41021 002	21542 575	1 904183	1	2 59	54	05104620001078	AA97220-01 05104620001078 14 N/A Serum-1 6 / Day 1 1667h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
14	N/A	6 / Day 1 0 1667h	42649 503	26110 573	1 633419	1	2 21	56	05104620001094	AA97220-01 05104620001094 14 N/A Serum- 1 6 / Day 1 1667h
14	N/A	6 / Day 1 0 1667h	163763 06	21451 808	7 633998	1	10 5	55	05104620001110	AA97220-01 05104620001110 14 N/A Serum- 1 6 / Day 1 1667h
14	N/A	7 / Day 1 0 25h	35289 883	17546 528	2 011217	1	2 74	58	05104620001079	AA97220-01 05104620001079 14 N/A Serum- 1 7 / Day 1 25h
14	N/A	7 / Day 1 0 25h	39379 708	17538 478	2 245332	1	3 06	59	05104620001095	AA97220-01 05104620001095 14 N/A Serum- 1 7 / Day 1 25h
14	N/A	7 / Day 1 0 25h	223057 657	31476 993	7 086371	1	9 75	57	05104620001111	AA97220-01 05104620001111 14 N/A Serum- 1 7 / Day 1 25h
14	N/A	8 / Day 1 0 333h	36066 963	17505 072	2 060372	1	2 80	60	05104620001080	AA97220-01 05104620001080 14 N/A Serum- 1 8 / Day 1 333h
14	N/A	8 / Day 1 0 333h	40820 155	18272 642	2 233949	1	3 04	61	05104620001096	AA97220-01 05104620001096 14 N/A Serum- 1 8 / Day 1 333h
14	N/A	8 / Day 1 0 333h	125787 383	17738 918	7 091040	1	9 75	62	05104620001112	AA97220-01 05104620001112 14 N/A Serum- 1 8 / Day 1 333h
14	N/A	9 / Day 1 0 5h	42454 205	16584 045	2 559943	1	3 49	64	05104620001081	AA97220-01 05104620001081 14 N/A Serum- 1 9 / Day 1 5h
14	N/A	9 / Day 1 0 5h	62108 941	24816 515	2 502726	1	3 41	66	05104620001097	AA97220-01 05104620001097 14 N/A Serum- 1 9 / Day 1 5h
14	N/A	9 / Day 1 0 5h	120040 125	16794 433	7 147614	1	9 83	65	05104620001113	AA97220-01 05104620001113 14 N/A Serum- 1 9 / Day 1 5h
14	N/A	10 / Day 1 0 75h	32042 007	16504 025	1 941466	1	2 64	68	05104620001082	AA97220-01 05104620001082 14 N/A Serum- 1 10 / Day 1 75h
14	N/A	10 / Day 1 0 75h	46920 757	17195 983	2 728588	1	3 73	69	05104620001098	AA97220-01 05104620001098 14 N/A Serum- 1 10 / Day 1 75h
14	N/A	10 / Day 1 0 75h	100929 595	15743 482	6 410881	1	8 81	67	05104620001114	AA97220-01 05104620001114 14 N/A Serum- 1 10 / Day 1 75h
14	N/A	11 / Day 1 1h	39330 023	21326 352	1 844198	1	2 50	72	05104620001083	AA97220-01 05104620001083 14 N/A Serum- 1 11 / Day 1 1h
14	N/A	11 / Day 1 1h	39157 462	17299 722	2 263473	1	3 08	70	05104620001099	AA97220-01 05104620001099 14 N/A Serum- 1 11 / Day 1 1h
14	N/A	11 / Day 1 1h	99195 208	16830 35	5 893829	1	8 10	71	05104620001115	AA97220-01 05104620001115 14 N/A Serum- 1 11 / Day 1 1h
14	N/A	12 / Day 1 1 25h	37143 478	20902 023	1 777028	1	2 41	75	05104620001084	AA97220-01 05104620001084 14 N/A Serum- 1 12 / Day 1 1 25h
14	N/A	12 / Day 1 1 25h	105550 542	19319 175	5 463512	1	7 51	73	05104620001116	AA97220-01 05104620001116 14 N/A Serum- 1 12 / Day 1 1 25h
14	N/A	13 / Day 1 1 5h	57075 037	37716 566	1 513262	1	2 05	78	05104620001085	AA97220-01 05104620001085 14 N/A Serum- 1 13 / Day 1 1 5h
14	N/A	13 / Day 1 1 5h	88655 938	43538 143	2 036282	1	2 77	76	05104620001101	AA97220-01 05104620001101 14 N/A Serum- 1 13 / Day 1 1 5h
14	N/A	13 / Day 1 1 5h	161261 462	34012 417	4 741253	1	6 51	77	05104620001117	AA97220-01 05104620001117 14 N/A Serum- 1 13 / Day 1 1 5h
14	N/A	14 / Day 1 2h	46513 684	39113 373	1 189202	1	1 60	80	05104620001086	AA97220-01 05104620001086 14 N/A Serum- 1 14 / Day 1 2h
14	N/A	14 / Day 1 2h	65907 908	35309 273	1 866589	1	2 54	81	05104620001102	AA97220-01 05104620001102 14 N/A Serum- 1 14 / Day 1 2h
14	N/A	14 / Day 1 2h	142132 565	38571 293	3 684931	1	5 05	79	05104620001118	AA97220-01 05104620001118 14 N/A Serum- 1 14 / Day 1 2h
14	N/A	15 / Day 1 2 5h	60036 21	53008 507	1 132577	1	1 52	84	05104620001087	AA97220-01 05104620001087 14 N/A Serum- 1 15 / Day 1 2 5h
14	N/A	15 / Day 1 2 5h	79513 966	54785 556	1 451367	1	1 96	83	05104620001103	AA97220-01 05104620001103 14 N/A Serum- 1 15 / Day 1 2 5h
14	N/A	15 / Day 1 2 5h	137447 513	38365 324	3 582597	1	4 91	82	05104620001119	AA97220-01 05104620001119 14 N/A Serum- 1 15 / Day 1 2 5h
14	N/A	16 / Day 1 3h	52897 632	57132 718	*0 925873	1	*1 24	87	05104620001088	AA97220-01 05104620001088 14 N/A Serum- 1 16 / Day 1 3h
14	N/A	16 / Day 1 3h	72318 54	52560 12	1 375920	1	1 86	85	05104620001104	AA97220-01 05104620001104 14 N/A Serum- 1 16 / Day 1 3h
14	N/A	16 / Day 1 3h	161306 618	51985 075	3 102941	1	4 24	86	05104620001120	AA97220-01 05104620001120 14 N/A Serum- 1 16 / Day 1 3h

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)

AAR - Concentration Found is Greater than 50 0 (Highest Standard)

* - Sample Rejected

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 17
 Serum, Concentration of Nicotine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		0	26814 887	0 000000	-0 0339		-0 0339	0 0
9	0 00		0	26936 154	0 000000	-0 0339			
10	0 500	4 00000	10450 228	26867 27	0 388958	0 504	0 8		
11	1 00	1 00000	17831 997	24334 558	0 732785	0 979	-2 1		
12	2 00	0 250000	41421 762	27736 143	1 493422	2 03	1 5		
13	4 00	0 0625000	67003 27	23316 737	2 873613	3 94	-1 5		
14	8 00	0 0156250	140239 614	23532 967	5 959283	8 21	2 6		
15	10 0	0 0100000	179592 99	25495 527	7 044098	9 71	-2 9		
16	20 0	0 00250000	364239 967	25092 173	14 516079	20 0	0 0		
17	40 0	0 000625000	709169 127	23529 742	30 139265	41 6	4 0		
18	50 0	0 000400000	803984 857	22830 03	35 216110	48 7	-2 6		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:
 Slope = 0 723232570
 Intercept = 0 0244840477
 R-Squared = 0 9992

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)
 AAR - Concentration Found is Greater than 50 0 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 17
Serum, Concentration of Nicotine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	1036302 419	29220 67	35 464704	1	49 0		48 4		1 4
2	0 00	1129984 773	32324 248	34 957805	1	48 3				
3	0 00	911082 852	25968 077	35 084725	1	48 5				
4	0 00	943019 937	27171 817	34 705811	1	48 0				
5	0 00	837583 578	24235 615	34 560030	1	47 8				
91	0 00	845776 422	23499 1	35 991864	1	49 7				
92	0 00	721294 522	20832 455	34 623597	1	47 8				
30	1 50	23673 192	23209 237	1 019990	1	1 38	-8 0	1 44	-4 0	5 9
63	1 50	25757 38	23167 235	1 111802	1	1 50	0 0			
41	8 00	152851 818	27065 204	5 647540	1	7 77	-2 9	7 73	-3 4	0 7
74	8 00	192838 884	34541 251	5 582858	1	7 69	-3 9			
52	37 5	648536 593	22742 203	28 516876	1	39 4	5 1	38 5	2 7	3 5
89	37 5	838740 271	30923 69	27 122904	1	37 5	0 0			

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)
AAR - Concentration Found is Greater than 50 0 (Highest Standard)

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 17
Serum, Concentration of Nicotine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
14	N/A	1 / Day 1 - 0 0333h	14280 955	23440 817	0 609235	1	0 809	21	05104620001041	AA97220-01 05104620001041 14 N/A Serum-1 1 / Day 1 - 0333h
14	N/A	1 / Day 1 - 0 0333h	12438 735	23598 308	0 527103	1	0 695	20	05104620001057	AA97220-01 05104620001057 14 N/A Serum-1 1 / Day 1 - 0333h
14	N/A	2 / Day 1 0h	12399 93	24316 69	0 509935	1	0 671	22	05104620001042	AA97220-01 05104620001042 14 N/A Serum-1 2 / Day 1 0h
14	N/A	2 / Day 1 0h	10452 232	24406 187	0 428262	1	0 558	23	05104620001058	AA97220-01 05104620001058 14 N/A Serum-1 2 / Day 1 0h
14	N/A	3 / Day 1 0 05h	14126 795	27151 145	0 520302	1	0 686	25	05104620001043	AA97220-01 05104620001043 14 N/A Serum-1 3 / Day 1 05h
14	N/A	3 / Day 1 0 05h	22844 038	25806 515	0 885204	1	1 19	24	05104620001059	AA97220-01 05104620001059 14 N/A Serum-1 3 / Day 1 05h
14	N/A	4 / Day 1 0 0833h	14463 762	25513 603	0 566904	1	0 750	26	05104620001044	AA97220-01 05104620001044 14 N/A Serum-1 4 / Day 1 0833h
14	N/A	4 / Day 1 0 0833h	33982 315	20483 803	1 658985	1	2 26	27	05104620001060	AA97220-01 05104620001060 14 N/A Serum-1 4 / Day 1 0833h
14	N/A	5 / Day 1 0 125h	18189 462	25820 925	0 704447	1	0 940	28	05104620001045	AA97220-01 05104620001045 14 N/A Serum-1 5 / Day 1 125h
14	N/A	5 / Day 1 0 125h	36406 537	27307 159	1 333223	1	1 81	29	05104620001061	AA97220-01 05104620001061 14 N/A Serum-1 5 / Day 1 125h
14	N/A	6 / Day 1 0 1667h	45868 242	45668 495	1 004374	1	1 35	32	05104620001046	AA97220-01 05104620001046 14 N/A Serum-1 6 / Day 1 1667h
14	N/A	6 / Day 1 0 1667h	38070 64	27875 77	1 365725	1	1 85	31	05104620001062	AA97220-01 05104620001062 14 N/A Serum-1 6 / Day 1 1667h
14	N/A	7 / Day 1 0 25h	25687 782	22466 915	1 143360	1	1 55	34	05104620001047	AA97220-01 05104620001047 14 N/A Serum-1 7 / Day 1 25h
14	N/A	7 / Day 1 0 25h	38214 665	22453 705	1 701931	1	2 32	33	05104620001063	AA97220-01 05104620001063 14 N/A Serum-1 7 / Day 1 25h
14	N/A	8 / Day 1 0 333h	26353 515	21067 767	1 250893	1	1 70	35	05104620001048	AA97220-01 05104620001048 14 N/A Serum-1 8 / Day 1 333h
14	N/A	8 / Day 1 0 333h	38041 317	22673 273	1 677804	1	2 29	36	05104620001064	AA97220-01 05104620001064 14 N/A Serum-1 8 / Day 1 333h
14	N/A	9 / Day 1 0 5h	35681 171	22488 183	1 586663	1	2 16	37	05104620001049	AA97220-01 05104620001049 14 N/A Serum-1 9 / Day 1 5h
14	N/A	9 / Day 1 0 5h	45986 612	28607 827	1 607484	1	2 19	38	05104620001065	AA97220-01 05104620001065 14 N/A Serum-1 9 / Day 1 5h
14	N/A	10 / Day 1 0 75h	47512 93	23365 683	2 033449	1	2 78	40	05104620001050	AA97220-01 05104620001050 14 N/A Serum-1 10 / Day 1 75h
14	N/A	10 / Day 1 0 75h	48704 067	27469 92	1 772996	1	2 42	39	05104620001066	AA97220-01 05104620001066 14 N/A Serum-1 10 / Day 1 75h
14	N/A	11 / Day 1 1h	47505 299	25416 279	1 869089	1	2 55	43	05104620001051	AA97220-01 05104620001051 14 N/A Serum-1 11 / Day 1 1h
14	N/A	11 / Day 1 1h	38341 165	26394 572	1 452616	1	1 97	42	05104620001067	AA97220-01 05104620001067 14 N/A Serum-1 11 / Day 1 1h
14	N/A	12 / Day 1 1 25h	51751 63	28558 15	1 812149	1	2 47	45	05104620001052	AA97220-01 05104620001052 14 N/A Serum-1 12 / Day 1 1 25h
14	N/A	12 / Day 1 1 25h	34619 368	25713 027	1 346375	1	1 83	44	05104620001068	AA97220-01 05104620001068 14 N/A Serum-1 12 / Day 1 1 25h
14	N/A	13 / Day 1 1 5h	51705 45	29596 663	1 747003	1	2 38	46	05104620001053	AA97220-01 05104620001053 14 N/A Serum-1 13 / Day 1 1 5h
14	N/A	13 / Day 1 1 5h	35677 628	29631 182	1 204057	1	1 63	47	05104620001069	AA97220-01 05104620001069 14 N/A Serum-1 13 / Day 1 1 5h
14	N/A	14 / Day 1 2h	49374 767	30619 96	1 612503	1	2 20	48	05104620001054	AA97220-01 05104620001054 14 N/A Serum-1 14 / Day 1 2h
14	N/A	14 / Day 1 2h	41721 233	32185 495	1 296274	1	1 76	49	05104620001070	AA97220-01 05104620001070 14 N/A Serum-1 14 / Day 1 2h
14	N/A	15 / Day 1 2 5h	43552 728	29100 869	1 496613	1	2 04	50	05104620001055	AA97220-01 05104620001055 14 N/A Serum-1 15 / Day 1 2 5h
14	N/A	15 / Day 1 2 5h	37744 195	32608 4	1 157499	1	1 57	51	05104620001071	AA97220-01 05104620001071 14 N/A Serum-1 15 / Day 1 2 5h
14	N/A	16 / Day 1 3h	37214 532	29553 467	1 259227	1	1 71	53	05104620001056	AA97220-01 05104620001056 14 N/A Serum-1 16 / Day 1 3h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
14	N/A	16 / Day 1 3h	25637 912	23778 568	1 078194	1	1 46	54	05104620001072	AA97220-01 05104620001072 14 N/A Serum-1 16 / Day 1 3h
15	N/A	1 / Day 1 - 0 0333h	53182 703	18599 765	2 859321	1	3 92	56	05104620001169	AA97220-01 05104620001169 15 N/A Serum-1 1 / Day 1 - 0333h
15	N/A	1 / Day 1 - 0 0333h	19799 995	27690 695	0 715041	1	0 955	55	05104620001185	AA97220-01 05104620001185 15 N/A Serum-1 1 / Day 1 - 0333h
15	N/A	2 / Day 1 0h	69540 61	27076 303	2 568320	1	3 52	58	05104620001170	AA97220-01 05104620001170 15 N/A Serum-1 2 / Day 1 0h
15	N/A	2 / Day 1 0h	12609 16	22351 146	0 564139	1	0 746	57	05104620001186	AA97220-01 05104620001186 15 N/A Serum-1 2 / Day 1 0h
15	N/A	3 / Day 1 0 05h	76999 138	23722 071	3 245886	1	4 45	59	05104620001171	AA97220-01 05104620001171 15 N/A Serum-1 3 / Day 1 0 05h
15	N/A	3 / Day 1 0 05h	170917 728	25198 89	6 782748	1	9 34	60	05104620001187	AA97220-01 05104620001187 15 N/A Serum-1 3 / Day 1 0 05h
15	N/A	4 / Day 1 0 0833h	100649 402	23359 727	4 308672	1	5 92	61	05104620001172	AA97220-01 05104620001172 15 N/A Serum-1 4 / Day 1 0 0833h
15	N/A	4 / Day 1 0 0833h	226544 883	27672 255	8 186716	1	11 3	62	05104620001188	AA97220-01 05104620001188 15 N/A Serum-1 4 / Day 1 0 0833h
15	N/A	5 / Day 1 0 125h	138203 653	29945 283	4 615206	1	6 35	64	05104620001173	AA97220-01 05104620001173 15 N/A Serum-1 5 / Day 1 0 125h
15	N/A	5 / Day 1 0 125h	210198 27	21423 102	9 811757	1	13 5	65	05104620001189	AA97220-01 05104620001189 15 N/A Serum-1 5 / Day 1 0 125h
15	N/A	6 / Day 1 0 1667h	113059 005	23154 78	4 882750	1	6 72	66	05104620001174	AA97220-01 05104620001174 15 N/A Serum-1 6 / Day 1 0 1667h
15	N/A	6 / Day 1 0 1667h	286462 511	21961 12	13 044076	1	18 0	67	05104620001190	AA97220-01 05104620001190 15 N/A Serum-1 6 / Day 1 0 1667h
15	N/A	7 / Day 1 0 25h	136906 455	25354 242	5 399746	1	7 43	69	05104620001175	AA97220-01 05104620001175 15 N/A Serum-1 7 / Day 1 0 25h
15	N/A	7 / Day 1 0 25h	251568 915	25110 002	10 018674	1	13 8	68	05104620001191	AA97220-01 05104620001191 15 N/A Serum-1 7 / Day 1 0 25h
15	N/A	8 / Day 1 0 333h	99246 842	20337 905	4 879895	1	6 71	70	05104620001176	AA97220-01 05104620001176 15 N/A Serum-1 8 / Day 1 0 333h
15	N/A	8 / Day 1 0 333h	245542 686	26729 145	9 186328	1	12 7	71	05104620001192	AA97220-01 05104620001192 15 N/A Serum-1 8 / Day 1 0 333h
15	N/A	9 / Day 1 0 5h	170231 52	29191 663	5 831512	1	8 03	72	05104620001177	AA97220-01 05104620001177 15 N/A Serum-1 9 / Day 1 0 5h
15	N/A	9 / Day 1 0 5h	216157 452	28739 382	7 521298	1	10 4	73	05104620001193	AA97220-01 05104620001193 15 N/A Serum-1 9 / Day 1 0 5h
15	N/A	10 / Day 1 0 75h	202012 935	34012 852	5 939312	1	8 18	75	05104620001178	AA97220-01 05104620001178 15 N/A Serum-1 10 / Day 1 0 75h
15	N/A	10 / Day 1 0 75h	199245 286	30605 972	6 510013	1	8 97	76	05104620001194	AA97220-01 05104620001194 15 N/A Serum-1 10 / Day 1 0 75h
15	N/A	11 / Day 1 1h	145751 907	30010 423	4 856710	1	6 68	77	05104620001179	AA97220-01 05104620001179 15 N/A Serum-1 11 / Day 1 1h
15	N/A	11 / Day 1 1h	182141 71	30785 718	5 916435	1	8 15	78	05104620001195	AA97220-01 05104620001195 15 N/A Serum-1 11 / Day 1 1h
15	N/A	12 / Day 1 1 25h	142560 2	31735 167	4 492184	1	6 18	79	05104620001180	AA97220-01 05104620001180 15 N/A Serum-1 12 / Day 1 1 25h
15	N/A	12 / Day 1 1 25h	215353 685	44042 112	4 889722	1	6 73	80	05104620001196	AA97220-01 05104620001196 15 N/A Serum-1 12 / Day 1 1 25h
15	N/A	13 / Day 1 1 5h	138149 739	33084 832	4 175622	1	5 74	81	05104620001181	AA97220-01 05104620001181 15 N/A Serum-1 13 / Day 1 1 5h
15	N/A	13 / Day 1 1 5h	172659 47	35533 593	4 859049	1	6 68	82	05104620001197	AA97220-01 05104620001197 15 N/A Serum-1 13 / Day 1 1 5h
15	N/A	14 / Day 1 2h	113195 419	30902 071	3 663037	1	5 03	84	05104620001182	AA97220-01 05104620001182 15 N/A Serum-1 14 / Day 1 2h
15	N/A	14 / Day 1 2h	176269 926	39553 373	4 456508	1	6 13	83	05104620001198	AA97220-01 05104620001198 15 N/A Serum-1 14 / Day 1 2h
15	N/A	15 / Day 1 2 5h	133163 91	38178 638	3 487917	1	4 79	85	05104620001183	AA97220-01 05104620001183 15 N/A Serum-1 15 / Day 1 2 5h
15	N/A	15 / Day 1 2 5h	127276 134	35441 398	3 591171	1	4 93	86	05104620001199	AA97220-01 05104620001199 15 N/A Serum-1 15 / Day 1 2 5h
15	N/A	16 / Day 1 3h	115461 324	37921 018	3 044784	1	4 18	88	05104620001184	AA97220-01 05104620001184 15 N/A Serum-1 16 / Day 1 3h
15	N/A	16 / Day 1 3h	113023 333	32518 13	3 475702	1	4 77	87	05104620001200	AA97220-01 05104620001200 15 N/A Serum-1 16 / Day 1 3h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0.500 (Lowest Standard)

AAR - Concentration Found is Greater than 50.0 (Highest Standard)

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 18
 Serum, Concentration of Nicotine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		0	24540 872	0 000000	-0 0399		-0 0399	0 0
9	0 00		0	30267 275	0 000000	-0 0399			
10	0 500	4 00000	9710 16	25523 438	0 380441	0 492	-1 6		
11	1 00	1 00000	17253 15	22562 695	0 764676	1 03	3 0		
12	2 00	0 250000	38063 418	26203 5	1 452608	1 99	-0 5		
13	4 00	0 0625000	75411 862	25296 91	2 981070	4 13	3 3		
14	8 00	0 0156250	134190 503	23351 772	5 746481	7 99	-0 1		
15	10 0	0 0100000	187625 973	26870 933	6 982488	9 72	-2 8		
16	20 0	0 00250000	395050 501	27572 597	14 327649	20 0	0 0		
17	40 0	0 000625000	656162 318	22740 058	28 854910	40 3	0 8		
18	50 0	0 000400000	844517 171	24072 48	35 082267	49 0	-2 0		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:

Slope = 0 715210071

Intercept = 0 0285499574

R-Squared = 0 9994

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)

AAR - Concentration Found is Greater than 50 0 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 18
 Serum, Concentration of Nicotine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	961296 955	27391 907	35 094196	1	49 0		48 4		1 9
2	0 00	1113803 642	32465 163	34 307656	1	47 9				
3	0 00	948095 609	26965 638	35 159398	1	49 1				
4	0 00	1015690 695	29688 298	34 211820	1	47 8				
5	0 00	983106 688	28920 718	33 993163	1	47 5				
91	0 00	550452 702	16173 112	34 035052	1	47 5				
92	0 00	560635 385	15687 532	35 737641	1	49 9				
30	1 50	26676 29	24615 897	1 083702	1	1 48	-1 3	1 46	-2 7	2 4
63	1 50	12119 85	11550 745	1 049270	1	1 43	-4 7			
41	8 00	84112 448	15356 283	5 477396	1	7 62	-4 8	7 51	-6 1	2 1
74	8 00	67217 595	12627 168	5 323252	1	7 40	-7 5			
52	37 5	304729 433	11534 747	26 418389	1	36 9	-1 6	37 6	0 3	2 6
89	37 5	675462 649	24619 052	27 436582	1	38 3	2 1			

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)
 AAR - Concentration Found is Greater than 50 0 (Highest Standard)

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 18
Serum, Concentration of Nicotine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
15	N/A	1 / Day 1 - 0 0333h	66842 148	23439 058	2 851742	1	3 95	22	05104620001121	AA97220-01 05104620001121 15 N/A Serum-1 1 / Day 1 - 0333h
15	N/A	1 / Day 1 - 0 0333h	19852 845	26523 792	0 748492	1	1 01	20	05104620001137	AA97220-01 05104620001137 15 N/A Serum-1 1 / Day 1 - 0333h
15	N/A	1 / Day 1 - 0 0333h	16987 856	18604 583	0 913101	1	1 24	21	05104620001153	AA97220-01 05104620001153 15 N/A Serum-1 1 / Day 1 - 0333h
15	N/A	2 / Day 1 0h	39564 095	14926 623	2 650572	1	3 67	25	05104620001122	AA97220-01 05104620001122 15 N/A Serum-1 2 / Day 1 0h
15	N/A	2 / Day 1 0h	16510 118	22145 007	0 745546	1	1 00	23	05104620001138	AA97220-01 05104620001138 15 N/A Serum-1 2 / Day 1 0h
15	N/A	2 / Day 1 0h	22169 773	22703 458	0 976493	1	1 33	24	05104620001154	AA97220-01 05104620001154 15 N/A Serum-1 2 / Day 1 0h
15	N/A	3 / Day 1 0 05h	33774 613	16393 362	2 060262	1	2 84	27	05104620001123	AA97220-01 05104620001123 15 N/A Serum-1 3 / Day 1 05h
15	N/A	3 / Day 1 0 05h	13254 445	18803 667	0 704886	1	0 946	28	05104620001139	AA97220-01 05104620001139 15 N/A Serum-1 3 / Day 1 05h
15	N/A	3 / Day 1 0 05h	11600 157	12475 62	0 929826	1	1 26	26	05104620001155	AA97220-01 05104620001155 15 N/A Serum-1 3 / Day 1 05h
15	N/A	4 / Day 1 0 0833h	48852 143	23313 198	2 095472	1	2 89	32	05104620001124	AA97220-01 05104620001124 15 N/A Serum-1 4 / Day 1 0833h
15	N/A	4 / Day 1 0 0833h	14886 558	22195 107	0 670714	1	0 898	31	05104620001140	AA97220-01 05104620001140 15 N/A Serum-1 4 / Day 1 0833h
15	N/A	4 / Day 1 0 0833h	21368 145	21591 378	0 989661	1	1 34	29	05104620001156	AA97220-01 05104620001156 15 N/A Serum-1 4 / Day 1 0833h
15	N/A	5 / Day 1 0 125h	38672 942	19686 898	1 964400	1	2 71	34	05104620001125	AA97220-01 05104620001125 15 N/A Serum-1 5 / Day 1 125h
15	N/A	5 / Day 1 0 125h	18525 687	20578 988	0 900223	1	1 22	33	05104620001141	AA97220-01 05104620001141 15 N/A Serum-1 5 / Day 1 125h
15	N/A	5 / Day 1 0 125h	19846 368	16841 57	1 178416	1	1 61	35	05104620001157	AA97220-01 05104620001157 15 N/A Serum-1 5 / Day 1 125h
15	N/A	6 / Day 1 0 1667h	33266 277	14777 818	2 251095	1	3 11	38	05104620001126	AA97220-01 05104620001126 15 N/A Serum-1 6 / Day 1 1667h
15	N/A	6 / Day 1 0 1667h	18283 437	15734 307	1 162011	1	1 58	37	05104620001142	AA97220-01 05104620001142 15 N/A Serum-1 6 / Day 1 1667h
15	N/A	6 / Day 1 0 1667h	27041 798	18581 018	1 455345	1	1 99	36	05104620001158	AA97220-01 05104620001158 15 N/A Serum-1 6 / Day 1 1667h
15	N/A	7 / Day 1 0 25h	40792 413	14939 428	2 730520	1	3 78	42	05104620001127	AA97220-01 05104620001127 15 N/A Serum-1 7 / Day 1 25h
15	N/A	7 / Day 1 0 25h	22670 002	15347 592	1 477105	1	2 03	40	05104620001143	AA97220-01 05104620001143 15 N/A Serum-1 7 / Day 1 25h
15	N/A	7 / Day 1 0 25h	31180 257	14726 367	2 117308	1	2 92	39	05104620001159	AA97220-01 05104620001159 15 N/A Serum-1 7 / Day 1 25h
15	N/A	8 / Day 1 0 333h	93183 067	23118 377	4 030692	1	5 60	44	05104620001128	AA97220-01 05104620001128 15 N/A Serum-1 8 / Day 1 333h
15	N/A	8 / Day 1 0 333h	26299 732	16208 547	1 622584	1	2 23	45	05104620001144	AA97220-01 05104620001144 15 N/A Serum-1 8 / Day 1 333h
15	N/A	8 / Day 1 0 333h	31935 238	15700 78	2 033991	1	2 80	43	05104620001160	AA97220-01 05104620001160 15 N/A Serum-1 8 / Day 1 333h
15	N/A	9 / Day 1 0 5h	87619 533	17274 228	5 072269	1	7 05	48	05104620001129	AA97220-01 05104620001129 15 N/A Serum-1 9 / Day 1 5h
15	N/A	9 / Day 1 0 5h	45360 089	21612 987	2 098742	1	2 89	46	05104620001145	AA97220-01 05104620001145 15 N/A Serum-1 9 / Day 1 5h
15	N/A	9 / Day 1 0 5h	32954 237	12736 718	2 587341	1	3 58	47	05104620001161	AA97220-01 05104620001161 15 N/A Serum-1 9 / Day 1 5h
15	N/A	10 / Day 1 0 75h	75566 222	16184 865	4 668944	1	6 49	51	05104620001130	AA97220-01 05104620001130 15 N/A Serum-1 10 / Day 1 75h
15	N/A	10 / Day 1 0 75h	34757 353	13513 74	2 572001	1	3 56	50	05104620001146	AA97220-01 05104620001146 15 N/A Serum-1 10 / Day 1 75h
15	N/A	10 / Day 1 0 75h	35312 392	13201 21	2 674936	1	3 70	49	05104620001162	AA97220-01 05104620001162 15 N/A Serum-1 10 / Day 1 75h
15	N/A	11 / Day 1 1h	59303 317	12291 113	4 824894	1	6 71	53	05104620001131	AA97220-01 05104620001131 15 N/A Serum-1 11 / Day 1 1h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
15	N/A	11 / Day 1 1h	34448 716	15199 765	2 266398	1	3 13	54	05104620001147	AA97220-01 05104620001147 15 N/A Serum-1 11 / Day 1 1h
15	N/A	11 / Day 1 1h	31210 415	13775 617	2 265627	1	3 13	55	05104620001163	AA97220-01 05104620001163 15 N/A Serum-1 11 / Day 1 1h
15	N/A	12 / Day 1 1 25h	59648 917	15539 523	3 838529	1	5 33	56	05104620001132	AA97220-01 05104620001132 15 N/A Serum-1 12 / Day 1 1 25h
15	N/A	12 / Day 1 1 25h	45839 398	16668 055	2 750135	1	3 81	58	05104620001148	AA97220-01 05104620001148 15 N/A Serum-1 12 / Day 1 1 25h
15	N/A	12 / Day 1 1 25h	33742 433	17272 833	1 953497	1	2 69	57	05104620001164	AA97220-01 05104620001164 15 N/A Serum-1 12 / Day 1 1 25h
15	N/A	13 / Day 1 1 5h	66779 662	17285 795	3 863268	1	5 36	61	05104620001133	AA97220-01 05104620001133 15 N/A Serum-1 13 / Day 1 1 5h
15	N/A	13 / Day 1 1 5h	36499 242	15268 112	2 390554	1	3 30	59	05104620001149	AA97220-01 05104620001149 15 N/A Serum-1 13 / Day 1 1 5h
15	N/A	13 / Day 1 1 5h	33180 203	17169 047	1 932559	1	2 66	60	05104620001165	AA97220-01 05104620001165 15 N/A Serum-1 13 / Day 1 1 5h
15	N/A	14 / Day 1 2h	39985 658	12795 233	3 125043	1	4 33	64	05104620001134	AA97220-01 05104620001134 15 N/A Serum-1 14 / Day 1 2h
15	N/A	14 / Day 1 2h	25317 272	12943 37	1 956003	1	2 69	65	05104620001150	AA97220-01 05104620001150 15 N/A Serum-1 14 / Day 1 2h
15	N/A	14 / Day 1 2h	21238 807	10887 775	1 950702	1	2 69	62	05104620001166	AA97220-01 05104620001166 15 N/A Serum-1 14 / Day 1 2h
15	N/A	15 / Day 1 2 5h	50472 354	16944 085	2 978759	1	4 12	67	05104620001135	AA97220-01 05104620001135 15 N/A Serum-1 15 / Day 1 2 5h
15	N/A	15 / Day 1 2 5h	23359 537	12750 067	1 832111	1	2 52	66	05104620001151	AA97220-01 05104620001151 15 N/A Serum-1 15 / Day 1 2 5h
15	N/A	15 / Day 1 2 5h	32719 898	18352 61	1 782847	1	2 45	68	05104620001167	AA97220-01 05104620001167 15 N/A Serum-1 15 / Day 1 2 5h
15	N/A	16 / Day 1 3h	55374 743	20481 947	2 703588	1	3 74	70	05104620001136	AA97220-01 05104620001136 15 N/A Serum-1 16 / Day 1 3h
15	N/A	16 / Day 1 3h	28873 535	16184 193	1 784058	1	2 45	71	05104620001152	AA97220-01 05104620001152 15 N/A Serum-1 16 / Day 1 3h
15	N/A	16 / Day 1 3h	29216 825	18134 657	1 611104	1	2 21	69	05104620001168	AA97220-01 05104620001168 15 N/A Serum-1 16 / Day 1 3h
16	N/A	1 / Day 1 - 0 0333h	10940 352	12710 575	0 860728	1	1 16	72	05104620001265	AA97220-01 05104620001265 16 N/A Serum-1 1 / Day 1 - 0333h
16	N/A	2 / Day 1 0h	11223 852	10695 003	*1 049448	1	*1 43	73	05104620001266	AA97220-01 05104620001266 16 N/A Serum-1 2 / Day 1 0h
16	N/A	3 / Day 1 0 05h	107032 263	9702 927	*11 030925	1	*15 4	75	05104620001267	AA97220-01 05104620001267 16 N/A Serum-1 3 / Day 1 05h
16	N/A	4 / Day 1 0 0833h	223123 244	13796 217	16 172784	1	22 6	76	05104620001268	AA97220-01 05104620001268 16 N/A Serum-1 4 / Day 1 0833h
16	N/A	5 / Day 1 0 125h	156851 294	11766 538	13 330284	1	18 6	77	05104620001269	AA97220-01 05104620001269 16 N/A Serum-1 5 / Day 1 125h
16	N/A	6 / Day 1 0 1667h	129095 167	12682 623	10 178901	1	14 2	78	05104620001270	AA97220-01 05104620001270 16 N/A Serum-1 6 / Day 1 1667h
16	N/A	7 / Day 1 0 25h	101939 29	12297 314	8 289557	1	11 6	79	05104620001271	AA97220-01 05104620001271 16 N/A Serum-1 7 / Day 1 25h
16	N/A	8 / Day 1 0 333h	92990 08	11540 43	8 057766	1	11 2	80	05104620001272	AA97220-01 05104620001272 16 N/A Serum-1 8 / Day 1 333h
16	N/A	9 / Day 1 0 5h	76207 73	12742 194	5 980738	1	8 32	81	05104620001273	AA97220-01 05104620001273 16 N/A Serum-1 9 / Day 1 5h
16	N/A	10 / Day 1 0 75h	73364 557	14232 065	5 154878	1	7 17	82	05104620001274	AA97220-01 05104620001274 16 N/A Serum-1 10 / Day 1 75h
16	N/A	11 / Day 1 1h	73852 085	15128 352	4 881701	1	6 79	83	05104620001275	AA97220-01 05104620001275 16 N/A Serum-1 11 / Day 1 1h
16	N/A	12 / Day 1 1 25h	54640 077	13259 067	4 120959	1	5 72	84	05104620001276	AA97220-01 05104620001276 16 N/A Serum-1 12 / Day 1 1 25h
16	N/A	13 / Day 1 1 5h	52577 82	12682 997	4 145536	1	5 76	85	05104620001277	AA97220-01 05104620001277 16 N/A Serum-1 13 / Day 1 1 5h
16	N/A	14 / Day 1 2h	40071 551	12216 15	3 280211	1	4 55	86	05104620001278	AA97220-01 05104620001278 16 N/A Serum-1 14 / Day 1 2h
16	N/A	15 / Day 1 2 5h	62185 995	19037 177	3 266555	1	4 53	87	05104620001279	AA97220-01 05104620001279 16 N/A Serum-1 15 / Day 1 2 5h
16	N/A	16 / Day 1 3h	47463 125	22575 269	2 102439	1	2 90	88	05104620001280	AA97220-01 05104620001280 16 N/A Serum-1 16 / Day 1 3h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0.500 (Lowest Standard)

AAR - Concentration Found is Greater than 50.0 (Highest Standard)

* - Sample Rejected

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 19
 Serum, Concentration of Nicotine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		0	299662 541	0 000000	0 0311		0 0311	0 0
9	0 00		0	295976 395	0 000000	0 0311			
10	0 500	4 00000	31787 29	264233 012	0 120300	0 495	-1 0		
11	1 00	1 00000	79085 646	323032 094	0 244823	0 975	-2 5		
12	2 00	0 250000	162395 517	288315 916	0 563255	2 20	10 0		
13	4 00	0 0625000	293175 652	288866 029	1 014919	3 95	-1 3		
14	8 00	0 0156250	610057 874	290546 797	2 099689	8 13	1 6		
15	10 0	0 0100000	762830 356	304661 55	2 503862	9 69	-3 1		
16	20 0	0 00250000	1326792 504	262812 263	5 048442	19 5	-2 5		
17	40 0	0 000625000	2968972 699	290510 404	10 219850	39 4	-1 5		
18	50 0	0 000400000	3498870 251	269794 487	12 968650	50 0	0 0		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:
 Slope = 0 259302097
 Intercept = -0 00805895441
 R-Squared = 0 9978

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)
 AAR - Concentration Found is Greater than 50 0 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 19
Serum, Concentration of Nicotine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	3675307 305	296835 148	12 381645	1	47 8		49 3		2 4
2	0 00	3424513 145	264631 433	12 940689	1	49 9				
3	0 00	3898002 612	301378 614	12 933906	1	49 9				
4	0 00	3766699 672	287658 702	13 094336	1	50 5				
5	0 00	3821637 738	302177 195	12 647009	1	48 8				
91	0 00	3608242 473	291838 913	12 363815	1	47 7				
92	0 00	3568725 275	274461 825	13 002629	1	50 2				
30	1 50	92859 542	246907 985	0 376090	1	1 48	-1 3	1 42	-5 3	6 5
63	1 50	104148 02	303662 022	0 342973	1	1 35	-10 0			
41	8 00	523226 868	272275 073	1 921685	1	7 44	-7 0	7 48	-6 5	0 8
74	8 00	575844 012	296636 348	1 941246	1	7 52	-6 0			
52	37 5	2607342 292	260063 84	10 025778	1	38 7	3 2	38 0	1 3	2 8
89	37 5	2600029 679	269416 315	9 650602	1	37 2	-0 8			

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)
AAR - Concentration Found is Greater than 50 0 (Highest Standard)

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 19
Serum, Concentration of Nicotine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
16	N/A	1 / Day 1 - 0 0333h	131385 411	285195 031	0 460686	1	1 81	23	05104620001201	AA97220-01 05104620001201 16 N/A Serum-1 1 / Day 1 - 0333h
16	N/A	1 / Day 1 - 0 0333h	119833 435	292475 217	0 409722	1	1 61	21	05104620001217	AA97220-01 05104620001217 16 N/A Serum-1 1 / Day 1 - 0333h
16	N/A	1 / Day 1 - 0 0333h	87825 909	279502 515	0 314222	1	1 24	20	05104620001233	AA97220-01 05104620001233 16 N/A Serum-1 1 / Day 1 - 0333h
16	N/A	1 / Day 1 - 0 0333h	106433 962	302075 568	0 352342	1	1 39	22	05104620001249	AA97220-01 05104620001249 16 N/A Serum-1 1 / Day 1 - 0333h
16	N/A	2 / Day 1 0h	81509 494	184313 327	0 442233	1	1 74	26	05104620001202	AA97220-01 05104620001202 16 N/A Serum-1 2 / Day 1 0h
16	N/A	2 / Day 1 0h	125748 293	311147 488	0 404144	1	1 59	27	05104620001218	AA97220-01 05104620001218 16 N/A Serum-1 2 / Day 1 0h
16	N/A	2 / Day 1 0h	86068 225	292205 665	0 294547	1	1 17	25	05104620001234	AA97220-01 05104620001234 16 N/A Serum-1 2 / Day 1 0h
16	N/A	2 / Day 1 0h	116805 323	302592 128	0 386016	1	1 52	24	05104620001250	AA97220-01 05104620001250 16 N/A Serum-1 2 / Day 1 0h
16	N/A	3 / Day 1 0 05h	142810 638	312432 087	0 457093	1	1 79	28	05104620001203	AA97220-01 05104620001203 16 N/A Serum-1 3 / Day 1 05h
16	N/A	3 / Day 1 0 05h	108102 583	283632 181	0 381137	1	1 50	31	05104620001219	AA97220-01 05104620001219 16 N/A Serum-1 3 / Day 1 05h
16	N/A	3 / Day 1 0 05h	84160 163	277792 82	0 302960	1	1 20	29	05104620001235	AA97220-01 05104620001235 16 N/A Serum-1 3 / Day 1 05h
16	N/A	3 / Day 1 0 05h	104490 015	275966 92	0 378632	1	1 49	32	05104620001251	AA97220-01 05104620001251 16 N/A Serum-1 3 / Day 1 05h
16	N/A	4 / Day 1 0 0833h	148771 221	256367 905	0 580304	1	2 27	34	05104620001204	AA97220-01 05104620001204 16 N/A Serum-1 4 / Day 1 0833h
16	N/A	4 / Day 1 0 0833h	149634 394	289335 11	0 517166	1	2 03	35	05104620001220	AA97220-01 05104620001220 16 N/A Serum-1 4 / Day 1 0833h
16	N/A	4 / Day 1 0 0833h	109571 818	252151 361	0 434548	1	1 71	33	05104620001236	AA97220-01 05104620001236 16 N/A Serum-1 4 / Day 1 0833h
16	N/A	4 / Day 1 0 0833h	152443 327	268786 885	0 567153	1	2 22	36	05104620001252	AA97220-01 05104620001252 16 N/A Serum-1 4 / Day 1 0833h
16	N/A	5 / Day 1 0 125h	161339 33	234492 285	0 688037	1	2 68	38	05104620001205	AA97220-01 05104620001205 16 N/A Serum-1 5 / Day 1 125h
16	N/A	5 / Day 1 0 125h	187671 867	262699 078	0 714399	1	2 79	40	05104620001221	AA97220-01 05104620001221 16 N/A Serum-1 5 / Day 1 125h
16	N/A	5 / Day 1 0 125h	173419 188	245603 344	0 706095	1	2 75	39	05104620001237	AA97220-01 05104620001237 16 N/A Serum-1 5 / Day 1 125h
16	N/A	5 / Day 1 0 125h	195929 679	244358 887	0 801811	1	3 12	37	05104620001253	AA97220-01 05104620001253 16 N/A Serum-1 5 / Day 1 125h
16	N/A	6 / Day 1 0 1667h	228630 042	279412 865	0 818252	1	3 19	45	05104620001206	AA97220-01 05104620001206 16 N/A Serum-1 6 / Day 1 1667h
16	N/A	6 / Day 1 0 1667h	205710 432	249605 197	0 824143	1	3 21	44	05104620001222	AA97220-01 05104620001222 16 N/A Serum-1 6 / Day 1 1667h
16	N/A	6 / Day 1 0 1667h	210393 089	259220 21	0 811638	1	3 16	43	05104620001238	AA97220-01 05104620001238 16 N/A Serum-1 6 / Day 1 1667h
16	N/A	6 / Day 1 0 1667h	229301 19	238034 958	0 963309	1	3 75	42	05104620001254	AA97220-01 05104620001254 16 N/A Serum-1 6 / Day 1 1667h
16	N/A	7 / Day 1 0 25h	290501 204	268643 933	1 081361	1	4 20	47	05104620001207	AA97220-01 05104620001207 16 N/A Serum-1 7 / Day 1 25h
16	N/A	7 / Day 1 0 25h	251223 65	287102 158	0 875032	1	3 41	48	05104620001223	AA97220-01 05104620001223 16 N/A Serum-1 7 / Day 1 25h
16	N/A	7 / Day 1 0 25h	258757 823	274291 61	0 943368	1	3 67	46	05104620001239	AA97220-01 05104620001239 16 N/A Serum-1 7 / Day 1 25h
16	N/A	7 / Day 1 0 25h	283851 275	267611 628	1 060684	1	4 12	49	05104620001255	AA97220-01 05104620001255 16 N/A Serum-1 7 / Day 1 25h
16	N/A	8 / Day 1 0 333h	326781 148	253781 055	1 287650	1	5 00	53	05104620001208	AA97220-01 05104620001208 16 N/A Serum-1 8 / Day 1 333h
16	N/A	8 / Day 1 0 333h	225788 471	271103 288	0 832850	1	3 24	51	05104620001224	AA97220-01 05104620001224 16 N/A Serum-1 8 / Day 1 333h
16	N/A	8 / Day 1 0 333h	269530 9	240965 897	1 118544	1	4 34	54	05104620001240	AA97220-01 05104620001240 16 N/A Serum-1 8 / Day 1 333h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
16	N/A	8 / Day 1 0 333h	280878 026	262112 715	1 071593	1	4 16	50	05104620001256	AA97220-01 05104620001256 16 N/A Serum- 1 8 / Day 1 333h
16	N/A	9 / Day 1 0 5h	514719 021	278652 177	1 847174	1	7 15	58	05104620001209	AA97220-01 05104620001209 16 N/A Serum- 1 9 / Day 1 5h
16	N/A	9 / Day 1 0 5h	244217 784	246281 746	0 991620	1	3 86	55	05104620001225	AA97220-01 05104620001225 16 N/A Serum- 1 9 / Day 1 5h
16	N/A	9 / Day 1 0 5h	298774 356	244723 851	1 220863	1	4 74	56	05104620001241	AA97220-01 05104620001241 16 N/A Serum- 1 9 / Day 1 5h
16	N/A	9 / Day 1 0 5h	241435 936	244203 994	0 988665	1	3 84	57	05104620001257	AA97220-01 05104620001257 16 N/A Serum- 1 9 / Day 1 5h
16	N/A	10 / Day 1 0 75h	717619 322	262222 629	2 736680	1	10 6	62	05104620001210	AA97220-01 05104620001210 16 N/A Serum- 1 10 / Day 1 75h
16	N/A	10 / Day 1 0 75h	268923 981	289121 835	0 930141	1	3 62	60	05104620001226	AA97220-01 05104620001226 16 N/A Serum- 1 10 / Day 1 75h
16	N/A	10 / Day 1 0 75h	290815 587	290059 284	1 002607	1	3 90	61	05104620001242	AA97220-01 05104620001242 16 N/A Serum- 1 10 / Day 1 75h
16	N/A	10 / Day 1 0 75h	270909 937	254822 48	1 063132	1	4 13	59	05104620001258	AA97220-01 05104620001258 16 N/A Serum- 1 10 / Day 1 75h
16	N/A	11 / Day 1 1h	649197 488	297551 046	2 181802	1	8 45	66	05104620001211	AA97220-01 05104620001211 16 N/A Serum- 1 11 / Day 1 1h
16	N/A	11 / Day 1 1h	265399 644	281612 95	0 942427	1	3 67	64	05104620001227	AA97220-01 05104620001227 16 N/A Serum- 1 11 / Day 1 1h
16	N/A	11 / Day 1 1h	246609 113	303033 853	0 813801	1	3 17	65	05104620001243	AA97220-01 05104620001243 16 N/A Serum- 1 11 / Day 1 1h
16	N/A	11 / Day 1 1h	249365 31	298242 872	0 836115	1	3 26	67	05104620001259	AA97220-01 05104620001259 16 N/A Serum- 1 11 / Day 1 1h
16	N/A	12 / Day 1 1 25h	479726 76	256908 888	1 867303	1	7 23	71	05104620001212	AA97220-01 05104620001212 16 N/A Serum- 1 12 / Day 1 1 25h
16	N/A	12 / Day 1 1 25h	248056 077	293260 986	0 845854	1	3 29	68	05104620001228	AA97220-01 05104620001228 16 N/A Serum- 1 12 / Day 1 1 25h
16	N/A	12 / Day 1 1 25h	190773 482	276019 96	0 691158	1	2 70	69	05104620001244	AA97220-01 05104620001244 16 N/A Serum- 1 12 / Day 1 1 25h
16	N/A	12 / Day 1 1 25h	186663 823	261880 787	0 712782	1	2 78	70	05104620001260	AA97220-01 05104620001260 16 N/A Serum- 1 12 / Day 1 1 25h
16	N/A	13 / Day 1 1 5h	426230 311	289763 262	1 470960	1	5 70	76	05104620001213	AA97220-01 05104620001213 16 N/A Serum- 1 13 / Day 1 1 5h
16	N/A	13 / Day 1 1 5h	214517 449	267589 187	0 801667	1	3 12	72	05104620001229	AA97220-01 05104620001229 16 N/A Serum- 1 13 / Day 1 1 5h
16	N/A	13 / Day 1 1 5h	186582 154	285415 333	0 653722	1	2 55	73	05104620001245	AA97220-01 05104620001245 16 N/A Serum- 1 13 / Day 1 1 5h
16	N/A	13 / Day 1 1 5h	223040 296	306642 172	0 727363	1	2 84	75	05104620001261	AA97220-01 05104620001261 16 N/A Serum- 1 13 / Day 1 1 5h
16	N/A	14 / Day 1 2h	442442 64	288535 592	1 533407	1	5 94	79	05104620001214	AA97220-01 05104620001214 16 N/A Serum- 1 14 / Day 1 2h
16	N/A	14 / Day 1 2h	197764 449	289172 348	0 683898	1	2 67	77	05104620001230	AA97220-01 05104620001230 16 N/A Serum- 1 14 / Day 1 2h
16	N/A	14 / Day 1 2h	171073 228	292721 305	0 584424	1	2 28	80	05104620001246	AA97220-01 05104620001246 16 N/A Serum- 1 14 / Day 1 2h
16	N/A	14 / Day 1 2h	187219 432	275367 157	0 679890	1	2 65	78	05104620001262	AA97220-01 05104620001262 16 N/A Serum- 1 14 / Day 1 2h
16	N/A	15 / Day 1 2 5h	371654 76	278578 377	1 334112	1	5 18	81	05104620001215	AA97220-01 05104620001215 16 N/A Serum- 1 15 / Day 1 2 5h
16	N/A	15 / Day 1 2 5h	151298 605	251232 353	0 602226	1	2 35	84	05104620001231	AA97220-01 05104620001231 16 N/A Serum- 1 15 / Day 1 2 5h
16	N/A	15 / Day 1 2 5h	138508 203	268054 48	0 516717	1	2 02	83	05104620001247	AA97220-01 05104620001247 16 N/A Serum- 1 15 / Day 1 2 5h
16	N/A	15 / Day 1 2 5h	171718 893	291927 043	0 588225	1	2 30	82	05104620001263	AA97220-01 05104620001263 16 N/A Serum- 1 15 / Day 1 2 5h
16	N/A	16 / Day 1 3h	256829 019	281738 38	0 911587	1	3 55	87	05104620001216	AA97220-01 05104620001216 16 N/A Serum- 1 16 / Day 1 3h
16	N/A	16 / Day 1 3h	135971 142	286962 83	0 473828	1	1 86	85	05104620001232	AA97220-01 05104620001232 16 N/A Serum- 1 16 / Day 1 3h
16	N/A	16 / Day 1 3h	118034 822	254179 194	0 464376	1	1 82	86	05104620001248	AA97220-01 05104620001248 16 N/A Serum- 1 16 / Day 1 3h
16	N/A	16 / Day 1 3h	148742 863	274589 246	0 541692	1	2 12	88	05104620001264	AA97220-01 05104620001264 16 N/A Serum- 1 16 / Day 1 3h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0.500 (Lowest Standard)

AAR - Concentration Found is Greater than 50.0 (Highest Standard)

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 20
Serum, Concentration of Nicotine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		7250 605	242016 816	0 029959	0 136		0 131	5 4
9	0 00		7222 064	262290 755	0 027535	0 126			
10	0 500	4 00000	37902 982	319442 461	0 118654	0 474	-5 2		
11	1 00	1 00000	100875 283	353993 619	0 284964	1 11	11 0		
12	2 00	0 250000	160541 619	305240 343	0 525952	2 03	1 5		
13	4 00	0 0625000	290224 64	287107 993	1 010855	3 88	-3 0		
14	8 00	0 0156250	579563 295	276829 999	2 093571	8 01	0 1		
15	10 0	0 0100000	641583 177	253817 917	2 527730	9 66	-3 4		
16	20 0	0 00250000	1364700 204	257692 124	5 295855	20 2	1 0		
17	40 0	0 000625000	2780824 479	263345 855	10 559591	40 3	0 8		
18	50 0	0 000400000	3165345 687	247484 195	12 790092	48 8	-2 4		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:
Slope = 0 262207671
Intercept = -0 00561512211
R-Squared = 0 9970

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)
AAR - Concentration Found is Greater than 50 0 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 20
Serum, Concentration of Nicotine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	4046656 704	325474 715	12 433091	1	47 4		47 5		1 1
2	0 00	4079956 766	323240 653	12 622041	1	48 2				
3	0 00	4713423 448	374559 513	12 583911	1	48 0				
4	0 00	4408813 859	355201 445	12 412151	1	47 4				
5	0 00	4680011 581	376144 743	12 442050	1	47 5				
91	0 00	3521171 285	288294 369	12 213805	1	46 6				
92	0 00	3670309 321	296703 963	12 370274	1	47 2				
30	1 50	143297 678	373144 958	0 384027	1	1 49	-0 7	1 49	-0 7	0 0
63	1 50	127973 535	332140 075	0 385300	1	1 49	-0 7			
41	8 00	478661 049	247851 647	1 931240	1	7 39	-7 6	7 51	-6 1	2 3
74	8 00	634732 279	318083 717	1 995488	1	7 63	-4 6			
52	37 5	3472697 136	367127 67	9 459099	1	36 1	-3 7	35 1	-6 4	4 0
89	37 5	2843481 391	317794 315	8 947553	1	34 1	-9 1			

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)
AAR - Concentration Found is Greater than 50 0 (Highest Standard)

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 20
Serum, Concentration of Nicotine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
17	N/A	1 / Day 1 - 0 0333h	108160 648	343954 169	0 314462	1	1 22	23	05104620001297	AA97220-01 05104620001297 17 N/A Serum-1 1 / Day 1 - 0333h
17	N/A	1 / Day 1 - 0 0333h	67218 902	335985 279	0 200065	1	0 784	21	05104620001313	AA97220-01 05104620001313 17 N/A Serum-1 1 / Day 1 - 0333h
17	N/A	1 / Day 1 - 0 0333h	216988 481	311135 185	0 697409	1	2 68	22	05104620001329	AA97220-01 05104620001329 17 N/A Serum-1 1 / Day 1 - 0333h
17	N/A	1 / Day 1 - 0 0333h	105605 936	316321 546	0 333856	1	1 29	20	05104620001345	AA97220-01 05104620001345 17 N/A Serum-1 1 / Day 1 - 0333h
17	N/A	2 / Day 1 0h	95913 678	323233 065	0 296732	1	1 15	24	05104620001298	AA97220-01 05104620001298 17 N/A Serum-1 2 / Day 1 0h
17	N/A	2 / Day 1 0h	64142 92	337273 962	0 190180	1	0 747	27	05104620001314	AA97220-01 05104620001314 17 N/A Serum-1 2 / Day 1 0h
17	N/A	2 / Day 1 0h	216015 687	348731 886	0 619432	1	2 38	26	05104620001330	AA97220-01 05104620001330 17 N/A Serum-1 2 / Day 1 0h
17	N/A	2 / Day 1 0h	136526 4	342561 298	0 398546	1	1 54	25	05104620001346	AA97220-01 05104620001346 17 N/A Serum-1 2 / Day 1 0h
17	N/A	3 / Day 1 0 05h	103397 815	331691 102	0 311729	1	1 21	31	05104620001299	AA97220-01 05104620001299 17 N/A Serum-1 3 / Day 1 05h
17	N/A	3 / Day 1 0 05h	80924 715	359662 705	0 225002	1	0 880	29	05104620001315	AA97220-01 05104620001315 17 N/A Serum-1 3 / Day 1 05h
17	N/A	3 / Day 1 0 05h	228107 326	360334 288	0 633044	1	2 44	28	05104620001331	AA97220-01 05104620001331 17 N/A Serum-1 3 / Day 1 05h
17	N/A	3 / Day 1 0 05h	1035906 651	293954 563	3 524037	1	13 5	32	05104620001347	AA97220-01 05104620001347 17 N/A Serum-1 3 / Day 1 05h
17	N/A	4 / Day 1 0 0833h	134763 39	306038 254	0 440348	1	1 70	36	05104620001300	AA97220-01 05104620001300 17 N/A Serum-1 4 / Day 1 0833h
17	N/A	4 / Day 1 0 0833h	81973 189	348086 598	0 235497	1	0 920	34	05104620001316	AA97220-01 05104620001316 17 N/A Serum-1 4 / Day 1 0833h
17	N/A	4 / Day 1 0 0833h	192708 753	317538 307	0 606883	1	2 34	33	05104620001332	AA97220-01 05104620001332 17 N/A Serum-1 4 / Day 1 0833h
17	N/A	4 / Day 1 0 0833h	802395 894	303137 997	2 646966	1	10 1	35	05104620001348	AA97220-01 05104620001348 17 N/A Serum-1 4 / Day 1 0833h
17	N/A	5 / Day 1 0 125h	128823 964	244741 649	0 526367	1	2 03	40	05104620001301	AA97220-01 05104620001301 17 N/A Serum-1 5 / Day 1 125h
17	N/A	5 / Day 1 0 125h	135771 379	273004 74	0 497322	1	1 92	39	05104620001317	AA97220-01 05104620001317 17 N/A Serum-1 5 / Day 1 125h
17	N/A	5 / Day 1 0 125h	211011 716	322073 174	0 655167	1	2 52	37	05104620001333	AA97220-01 05104620001333 17 N/A Serum-1 5 / Day 1 125h
17	N/A	5 / Day 1 0 125h	893926 137	284886 795	3 137829	1	12 0	38	05104620001349	AA97220-01 05104620001349 17 N/A Serum-1 5 / Day 1 125h
17	N/A	6 / Day 1 0 1667h	170661 782	310556 025	0 549536	1	2 12	45	05104620001302	AA97220-01 05104620001302 17 N/A Serum-1 6 / Day 1 1667h
17	N/A	6 / Day 1 0 1667h	183236 142	317184 432	0 577696	1	2 22	44	05104620001318	AA97220-01 05104620001318 17 N/A Serum-1 6 / Day 1 1667h
17	N/A	6 / Day 1 0 1667h	243273 791	365164 628	0 666203	1	2 56	43	05104620001334	AA97220-01 05104620001334 17 N/A Serum-1 6 / Day 1 1667h
17	N/A	6 / Day 1 0 1667h	1249759 954	303446 918	4 118546	1	15 7	42	05104620001350	AA97220-01 05104620001350 17 N/A Serum-1 6 / Day 1 1667h
17	N/A	7 / Day 1 0 25h	188633 621	299624 652	0 629566	1	2 42	48	05104620001303	AA97220-01 05104620001303 17 N/A Serum-1 7 / Day 1 25h
17	N/A	7 / Day 1 0 25h	250893 569	337885 888	0 742539	1	2 85	49	05104620001319	AA97220-01 05104620001319 17 N/A Serum-1 7 / Day 1 25h
17	N/A	7 / Day 1 0 25h	237962 369	348820 17	0 682192	1	2 62	46	05104620001335	AA97220-01 05104620001335 17 N/A Serum-1 7 / Day 1 25h
17	N/A	7 / Day 1 0 25h	1054565 267	356711 077	2 956357	1	11 3	47	05104620001351	AA97220-01 05104620001351 17 N/A Serum-1 7 / Day 1 25h
17	N/A	8 / Day 1 0 333h	206876 401	279988 515	0 738875	1	2 84	50	05104620001304	AA97220-01 05104620001304 17 N/A Serum-1 8 / Day 1 333h
17	N/A	8 / Day 1 0 333h	275602 947	334346 465	0 824303	1	3 17	54	05104620001320	AA97220-01 05104620001320 17 N/A Serum-1 8 / Day 1 333h
17	N/A	8 / Day 1 0 333h	210880 475	326033 73	0 646806	1	2 49	51	05104620001336	AA97220-01 05104620001336 17 N/A Serum-1 8 / Day 1 333h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
17	N/A	8 / Day 1 0 333h	910076 775	323863 06	2 810067	1	10 7	53	05104620001352	AA97220-01 05104620001352 17 N/A Serum-1 8 / Day 1 333h
17	N/A	9 / Day 1 0 5h	279581 933	320525 297	0 872262	1	3 35	58	05104620001305	AA97220-01 05104620001305 17 N/A Serum-1 9 / Day 1 5h
17	N/A	9 / Day 1 0 5h	274587 324	332952 2	0 824705	1	3 17	55	05104620001321	AA97220-01 05104620001321 17 N/A Serum-1 9 / Day 1 5h
17	N/A	9 / Day 1 0 5h	238549 093	311763 611	0 765160	1	2 94	56	05104620001337	AA97220-01 05104620001337 17 N/A Serum-1 9 / Day 1 5h
17	N/A	9 / Day 1 0 5h	858155 767	351751 853	2 439662	1	9 33	57	05104620001353	AA97220-01 05104620001353 17 N/A Serum-1 9 / Day 1 5h
17	N/A	10 / Day 1 0 75h	256551 778	348523 65	0 736110	1	2 83	60	05104620001306	AA97220-01 05104620001306 17 N/A Serum-1 10 / Day 1 75h
17	N/A	10 / Day 1 0 75h	242611 494	343734 64	0 705810	1	2 71	61	05104620001322	AA97220-01 05104620001322 17 N/A Serum-1 10 / Day 1 75h
17	N/A	10 / Day 1 0 75h	250931 967	311794 297	0 804800	1	3 09	62	05104620001338	AA97220-01 05104620001338 17 N/A Serum-1 10 / Day 1 75h
17	N/A	10 / Day 1 0 75h	538399 614	326910 18	1 646934	1	6 30	59	05104620001354	AA97220-01 05104620001354 17 N/A Serum-1 10 / Day 1 75h
17	N/A	11 / Day 1 1h	197537 158	310941 685	0 635287	1	2 44	64	05104620001307	AA97220-01 05104620001307 17 N/A Serum-1 11 / Day 1 1h
17	N/A	11 / Day 1 1h	169909 18	296475 89	0 573096	1	2 21	66	05104620001323	AA97220-01 05104620001323 17 N/A Serum-1 11 / Day 1 1h
17	N/A	11 / Day 1 1h	238730 745	332671 784	0 717616	1	2 76	65	05104620001339	AA97220-01 05104620001339 17 N/A Serum-1 11 / Day 1 1h
17	N/A	11 / Day 1 1h	460644 921	319601 744	1 441309	1	5 52	67	05104620001355	AA97220-01 05104620001355 17 N/A Serum-1 11 / Day 1 1h
17	N/A	12 / Day 1 1 25h	194040 682	362575 163	0 535174	1	2 06	68	05104620001308	AA97220-01 05104620001308 17 N/A Serum-1 12 / Day 1 1 25h
17	N/A	12 / Day 1 1 25h	125965 146	306827 797	0 410540	1	1 59	71	05104620001324	AA97220-01 05104620001324 17 N/A Serum-1 12 / Day 1 1 25h
17	N/A	12 / Day 1 1 25h	211600 673	325876 548	0 649328	1	2 50	70	05104620001340	AA97220-01 05104620001340 17 N/A Serum-1 12 / Day 1 1 25h
17	N/A	12 / Day 1 1 25h	426921 918	335196 097	1 273648	1	4 88	69	05104620001356	AA97220-01 05104620001356 17 N/A Serum-1 12 / Day 1 1 25h
17	N/A	13 / Day 1 1 5h	167994 684	331179 329	0 507262	1	1 96	73	05104620001309	AA97220-01 05104620001309 17 N/A Serum-1 13 / Day 1 1 5h
17	N/A	13 / Day 1 1 5h	102358 492	301754 25	0 339211	1	1 32	75	05104620001325	AA97220-01 05104620001325 17 N/A Serum-1 13 / Day 1 1 5h
17	N/A	13 / Day 1 1 5h	181282 164	290502 672	0 624029	1	2 40	76	05104620001341	AA97220-01 05104620001341 17 N/A Serum-1 13 / Day 1 1 5h
17	N/A	13 / Day 1 1 5h	321368 128	302775 735	1 061406	1	4 07	72	05104620001357	AA97220-01 05104620001357 17 N/A Serum-1 13 / Day 1 1 5h
17	N/A	14 / Day 1 2h	131718 286	293081 387	0 449426	1	1 74	78	05104620001310	AA97220-01 05104620001310 17 N/A Serum-1 14 / Day 1 2h
17	N/A	14 / Day 1 2h	126769 994	312574 266	0 405568	1	1 57	77	05104620001326	AA97220-01 05104620001326 17 N/A Serum-1 14 / Day 1 2h
17	N/A	14 / Day 1 2h	150181 742	310210 567	0 484128	1	1 87	80	05104620001342	AA97220-01 05104620001342 17 N/A Serum-1 14 / Day 1 2h
17	N/A	14 / Day 1 2h	285131 665	298955 612	0 953759	1	3 66	79	05104620001358	AA97220-01 05104620001358 17 N/A Serum-1 14 / Day 1 2h
17	N/A	15 / Day 1 2 5h	121018 175	305731 5	0 395832	1	1 53	83	05104620001311	AA97220-01 05104620001311 17 N/A Serum-1 15 / Day 1 2 5h
17	N/A	15 / Day 1 2 5h	114507 08	283903 272	0 403331	1	1 56	82	05104620001327	AA97220-01 05104620001327 17 N/A Serum-1 15 / Day 1 2 5h
17	N/A	15 / Day 1 2 5h	115246 443	306666 162	0 375804	1	1 45	84	05104620001343	AA97220-01 05104620001343 17 N/A Serum-1 15 / Day 1 2 5h
17	N/A	15 / Day 1 2 5h	238256 371	330494 945	0 720908	1	2 77	81	05104620001359	AA97220-01 05104620001359 17 N/A Serum-1 15 / Day 1 2 5h
17	N/A	16 / Day 1 3h	114785 51	330303 304	0 347515	1	1 35	86	05104620001312	AA97220-01 05104620001312 17 N/A Serum-1 16 / Day 1 3h
17	N/A	16 / Day 1 3h	103332 994	336357 764	0 307212	1	1 19	85	05104620001328	AA97220-01 05104620001328 17 N/A Serum-1 16 / Day 1 3h
17	N/A	16 / Day 1 3h	90795 911	251178 712	0 361479	1	1 40	88	05104620001344	AA97220-01 05104620001344 17 N/A Serum-1 16 / Day 1 3h
17	N/A	16 / Day 1 3h	221346 985	331933 474	0 666841	1	2 56	87	05104620001360	AA97220-01 05104620001360 17 N/A Serum-1 16 / Day 1 3h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0.500 (Lowest Standard)

AAR - Concentration Found is Greater than 50.0 (Highest Standard)

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 22
 Serum, Concentration of Nicotine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		0	51055 55	0 000000	-0 0119		0 0220	217 7
9	0 00		2541 6	51873 628	0 048996	0 0558			
10	0 500	4 00000	18479 872	50439 568	0 366376	0 494	-1 2		
11	1 00	1 00000	41300 262	57990 487	0 712190	0 972	-2 8		
12	2 00	0 250000	89685 494	55707 929	1 609923	2 21	10 5		
13	4 00	0 0625000	171210 644	58661 036	2 918643	4 02	0 5		
14	8 00	0 0156250	342994 228	58108 476	5 902654	8 14	1 8		
15	10 0	0 0100000	436452 755	62119 525	7 026016	9 69	-3 1		
16	20 0	0 00250000	813964 443	58071 277	14 016644	19 4	-3 0		
17	40 0	0 000625000	1558306 662	53990 297	28 862717	39 9	-0 3		
18	50 0	0 000400000	1941466 858	54872 5	35 381418	48 9	-2 2		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:
 Slope = 0 723874052
 Intercept = 0 00863872549
 R-Squared = 0 9975

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)
 AAR - Concentration Found is Greater than 50 0 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 22
 Serum, Concentration of Nicotine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	1792441 223	50504 406	35 490789	1	49 0		48 7		3 5
2	0 00	1958881 358	58228 369	33 641357	1	46 5				
3	0 00	2100850 87	60413 05	34 774786	1	48 0				
4	0 00	2117052 171	57645 983	36 725060	1	50 7				
5	0 00	2007869 934	56308 008	35 658692	1	49 2				
90	0 00	1955540 735	53042 601	36 867361	1	50 9				
91	0 00	2178064 776	64159 074	33 947884	1	46 9				
30	1 50	61387 672	59739 967	1 027581	1	1 41	-6 0	1 51	0 7	9 3
63	1 50	79279 473	67706 577	1 170927	1	1 61	7 3			
41	8 00	366395 014	67528 205	5 425807	1	7 48	-6 5	7 57	-5 4	1 6
74	8 00	474402 179	85504 127	5 548296	1	7 65	-4 4			
52	37 5	1819863 727	67626 308	26 910588	1	37 2	-0 8	37 8	0 8	2 1
88	37 5	1729481 429	62443 043	27 696943	1	38 3	2 1			

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)
 AAR - Concentration Found is Greater than 50 0 (Highest Standard)

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 22
Serum, Concentration of Nicotine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
08	N/A	1 / Day 1 -0 0333h	38158 013	59275 392	0 643741	1	0 877	23	05104620000561	AA97220-01 05104620000561 08 N/A Serum-1 1 / Day 1 - 0333h
08	N/A	1 / Day 1 -0 0333h	38798 343	58672 232	0 661273	1	0 902	22	05104620000577	AA97220-01 05104620000577 08 N/A Serum-1 1 / Day 1 - 0333h
08	N/A	1 / Day 1 -0 0333h	40121 653	56935 01	0 704692	1	0 962	20	05104620000593	AA97220-01 05104620000593 08 N/A Serum-1 1 / Day 1 - 0333h
08	N/A	1 / Day 1 -0 0333h	21892 239	60089 266	0 364329	1	BLQ<(0 500)	21	05104620000609	AA97220-01 05104620000609 08 N/A Serum-1 1 / Day 1 - 0333h
08	N/A	2 / Day 1 0h	48713 997	57277 897	0 850485	1	1 16	25	05104620000562	AA97220-01 05104620000562 08 N/A Serum-1 2 / Day 1 0h
08	N/A	2 / Day 1 0h	41467 828	61168 842	0 677924	1	0 925	24	05104620000578	AA97220-01 05104620000578 08 N/A Serum-1 2 / Day 1 0h
08	N/A	2 / Day 1 0h	40738 628	58630 205	0 694840	1	0 948	26	05104620000594	AA97220-01 05104620000594 08 N/A Serum-1 2 / Day 1 0h
08	N/A	2 / Day 1 0h	20094 493	53596 295	0 374923	1	0 506	27	05104620000610	AA97220-01 05104620000610 08 N/A Serum-1 2 / Day 1 0h
08	N/A	3 / Day 1 0 05h	43480 615	51767 39	0 839923	1	1 15	31	05104620000563	AA97220-01 05104620000563 08 N/A Serum-1 3 / Day 1 05h
08	N/A	3 / Day 1 0 05h	44560 883	61153 92	0 728668	1	0 995	28	05104620000579	AA97220-01 05104620000579 08 N/A Serum-1 3 / Day 1 05h
08	N/A	3 / Day 1 0 05h	37360 447	55229 552	0 676458	1	0 923	29	05104620000595	AA97220-01 05104620000595 08 N/A Serum-1 3 / Day 1 05h
08	N/A	3 / Day 1 0 05h	26246 583	59948 987	0 437815	1	0 593	32	05104620000611	AA97220-01 05104620000611 08 N/A Serum-1 3 / Day 1 05h
08	N/A	4 / Day 1 0 0833h	36176 272	58020 373	0 623510	1	0 849	33	05104620000564	AA97220-01 05104620000564 08 N/A Serum-1 4 / Day 1 0833h
08	N/A	4 / Day 1 0 0833h	46876 44	57217 803	0 819263	1	1 12	35	05104620000580	AA97220-01 05104620000580 08 N/A Serum-1 4 / Day 1 0833h
08	N/A	4 / Day 1 0 0833h	47309 175	63576 866	0 744126	1	1 02	36	05104620000596	AA97220-01 05104620000596 08 N/A Serum-1 4 / Day 1 0833h
08	N/A	4 / Day 1 0 0833h	39711 762	60531 238	0 656054	1	0 894	34	05104620000612	AA97220-01 05104620000612 08 N/A Serum-1 4 / Day 1 0833h
08	N/A	5 / Day 1 0 125h	54728 532	73431 358	0 745302	1	1 02	39	05104620000565	AA97220-01 05104620000565 08 N/A Serum-1 5 / Day 1 125h
08	N/A	5 / Day 1 0 125h	42570 336	63549 03	0 669882	1	0 913	37	05104620000581	AA97220-01 05104620000581 08 N/A Serum-1 5 / Day 1 125h
08	N/A	5 / Day 1 0 125h	54793 235	61374 237	0 892773	1	1 22	38	05104620000613	AA97220-01 05104620000613 08 N/A Serum-1 5 / Day 1 125h
08	N/A	6 / Day 1 0 1667h	47195 05	61119 105	0 772182	1	1 05	43	05104620000566	AA97220-01 05104620000566 08 N/A Serum-1 6 / Day 1 1667h
08	N/A	6 / Day 1 0 1667h	42666 88	60313 523	0 707418	1	0 965	44	05104620000582	AA97220-01 05104620000582 08 N/A Serum-1 6 / Day 1 1667h
08	N/A	6 / Day 1 0 1667h	65110 262	60444 456	1 077192	1	1 48	42	05104620000598	AA97220-01 05104620000598 08 N/A Serum-1 6 / Day 1 1667h
08	N/A	6 / Day 1 0 1667h	75273 575	71311 755	1 055556	1	1 45	40	05104620000614	AA97220-01 05104620000614 08 N/A Serum-1 6 / Day 1 1667h
08	N/A	7 / Day 1 0 25h	63025 31	59121 66	1 066027	1	1 46	48	05104620000567	AA97220-01 05104620000567 08 N/A Serum-1 7 / Day 1 25h
08	N/A	7 / Day 1 0 25h	51415 764	59694 315	0 861318	1	1 18	45	05104620000583	AA97220-01 05104620000583 08 N/A Serum-1 7 / Day 1 25h
08	N/A	7 / Day 1 0 25h	55477 422	57315 183	0 967936	1	1 33	47	05104620000599	AA97220-01 05104620000599 08 N/A Serum-1 7 / Day 1 25h
08	N/A	7 / Day 1 0 25h	71422 28	62219 283	1 147912	1	1 57	46	05104620000615	AA97220-01 05104620000615 08 N/A Serum-1 7 / Day 1 25h
08	N/A	8 / Day 1 0 333h	75988 433	61738 02	1 230821	1	1 69	51	05104620000568	AA97220-01 05104620000568 08 N/A Serum-1 8 / Day 1 333h
08	N/A	8 / Day 1 0 333h	52660 025	66093 14	0 796755	1	1 09	53	05104620000584	AA97220-01 05104620000584 08 N/A Serum-1 8 / Day 1 333h
08	N/A	8 / Day 1 0 333h	70761 95	63342 902	1 117125	1	1 53	49	05104620000600	AA97220-01 05104620000600 08 N/A Serum-1 8 / Day 1 333h
08	N/A	8 / Day 1 0 333h	81420 045	64512 758	1 262077	1	1 73	50	05104620000616	AA97220-01 05104620000616 08 N/A Serum-1 8 / Day 1 333h
08	N/A	9 / Day 1 0 5h	95965 768	70029 552	1 370361	1	1 88	55	05104620000569	AA97220-01 05104620000569 08 N/A Serum-1 9 / Day 1 5h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
08	N/A	9 / Day 1 0 5h	54442 177	60632 217	0 897908	1	1 23	56	05104620000585	AA97220-01 05104620000585 08 N/A Serum-1 9 / Day 1 5h
08	N/A	9 / Day 1 0 5h	84773 748	66697 375	1 271021	1	1 74	54	05104620000601	AA97220-01 05104620000601 08 N/A Serum-1 9 / Day 1 5h
08	N/A	9 / Day 1 0 5h	84311 972	62058 557	1 358587	1	1 86	57	05104620000617	AA97220-01 05104620000617 08 N/A Serum-1 9 / Day 1 5h
08	N/A	10 / Day 1 0 75h	98792 986	60867 975	1 623070	1	2 23	58	05104620000570	AA97220-01 05104620000570 08 N/A Serum-1 10 / Day 1 75h
08	N/A	10 / Day 1 0 75h	74506 409	67184 319	1 108985	1	1 52	60	05104620000586	AA97220-01 05104620000586 08 N/A Serum-1 10 / Day 1 75h
08	N/A	10 / Day 1 0 75h	92165 496	72750 587	1 266869	1	1 74	61	05104620000602	AA97220-01 05104620000602 08 N/A Serum-1 10 / Day 1 75h
08	N/A	10 / Day 1 0 75h	89612 913	68618 66	1 305955	1	1 79	59	05104620000618	AA97220-01 05104620000618 08 N/A Serum-1 10 / Day 1 75h
08	N/A	11 / Day 1 1h	96262 2	68962 367	1 395866	1	1 92	62	05104620000571	AA97220-01 05104620000571 08 N/A Serum-1 11 / Day 1 1h
08	N/A	11 / Day 1 1h	125641 008	78274 46	1 605134	1	2 21	64	05104620000587	AA97220-01 05104620000587 08 N/A Serum-1 11 / Day 1 1h
08	N/A	11 / Day 1 1h	93905 735	62198 202	1 509782	1	2 07	66	05104620000603	AA97220-01 05104620000603 08 N/A Serum-1 11 / Day 1 1h
08	N/A	11 / Day 1 1h	75880 014	67086 525	1 131077	1	1 55	65	05104620000619	AA97220-01 05104620000619 08 N/A Serum-1 11 / Day 1 1h
08	N/A	12 / Day 1 1 25h	87324 411	64408 021	1 355800	1	1 86	68	05104620000572	AA97220-01 05104620000572 08 N/A Serum-1 12 / Day 1 1 25h
08	N/A	12 / Day 1 1 25h	96150 548	61604 21	1 560779	1	2 14	69	05104620000588	AA97220-01 05104620000588 08 N/A Serum-1 12 / Day 1 1 25h
08	N/A	12 / Day 1 1 25h	95490 308	61003 113	1 565335	1	2 15	67	05104620000604	AA97220-01 05104620000604 08 N/A Serum-1 12 / Day 1 1 25h
08	N/A	12 / Day 1 1 25h	91026 775	81605 311	1 115452	1	1 53	70	05104620000620	AA97220-01 05104620000620 08 N/A Serum-1 12 / Day 1 1 25h
08	N/A	13 / Day 1 1 5h	113942 446	88810 085	1 282990	1	1 76	71	05104620000573	AA97220-01 05104620000573 08 N/A Serum-1 13 / Day 1 1 5h
08	N/A	13 / Day 1 1 5h	129017 187	87621 522	1 472437	1	2 02	73	05104620000589	AA97220-01 05104620000589 08 N/A Serum-1 13 / Day 1 1 5h
08	N/A	13 / Day 1 1 5h	126966 723	86467 652	1 468373	1	2 02	72	05104620000605	AA97220-01 05104620000605 08 N/A Serum-1 13 / Day 1 1 5h
08	N/A	13 / Day 1 1 5h	92773 722	86864 72	1 068025	1	1 46	75	05104620000621	AA97220-01 05104620000621 08 N/A Serum-1 13 / Day 1 1 5h
08	N/A	14 / Day 1 2h	92312 522	78650 663	1 173703	1	1 61	79	05104620000574	AA97220-01 05104620000574 08 N/A Serum-1 14 / Day 1 2h
08	N/A	14 / Day 1 2h	93301 787	79316 293	1 176326	1	1 61	78	05104620000590	AA97220-01 05104620000590 08 N/A Serum-1 14 / Day 1 2h
08	N/A	14 / Day 1 2h	104131 049	79124 445	1 316041	1	1 81	77	05104620000606	AA97220-01 05104620000606 08 N/A Serum-1 14 / Day 1 2h
08	N/A	14 / Day 1 2h	75124 613	83832 68	0 896126	1	1 23	76	05104620000622	AA97220-01 05104620000622 08 N/A Serum-1 14 / Day 1 2h
08	N/A	15 / Day 1 2 5h	92510 783	91052 868	1 016012	1	1 39	83	05104620000575	AA97220-01 05104620000575 08 N/A Serum-1 15 / Day 1 2 5h
08	N/A	15 / Day 1 2 5h	115917 849	90785 774	1 276828	1	1 75	82	05104620000591	AA97220-01 05104620000591 08 N/A Serum-1 15 / Day 1 2 5h
08	N/A	15 / Day 1 2 5h	103544 034	82514 854	1 254853	1	1 72	80	05104620000607	AA97220-01 05104620000607 08 N/A Serum-1 15 / Day 1 2 5h
08	N/A	15 / Day 1 2 5h	76262 878	83417 146	0 914235	1	1 25	81	05104620000623	AA97220-01 05104620000623 08 N/A Serum-1 15 / Day 1 2 5h
08	N/A	16 / Day 1 3h	86460 295	84890 574	1 018491	1	1 40	84	05104620000576	AA97220-01 05104620000576 08 N/A Serum-1 16 / Day 1 3h
08	N/A	16 / Day 1 3h	61530 447	60906 843	1 010239	1	1 38	87	05104620000592	AA97220-01 05104620000592 08 N/A Serum-1 16 / Day 1 3h
08	N/A	16 / Day 1 3h	56298 2	52579 22	1 070731	1	1 47	85	05104620000608	AA97220-01 05104620000608 08 N/A Serum-1 16 / Day 1 3h
08	N/A	16 / Day 1 3h	53482 041	63666 183	0 840038	1	1 15	86	05104620000624	AA97220-01 05104620000624 08 N/A Serum-1 16 / Day 1 3h

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)
AAR - Concentration Found is Greater than 50 0 (Highest Standard)

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 23
 Serum, Concentration of Nicotine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		0	272706 487	0 000000	-0 00852		-0 00852	0 0
9	0 00		0	257957 058	0 000000	-0 00852			
10	0 500	4 00000	36706 31	276788 28	0 132615	0 524	4 8		
11	1 00	1 00000	63779 794	280152 11	0 227661	0 905	-9 5		
12	2 00	0 250000	146899 65	293194 1	0 501032	2 00	0 0		
13	4 00	0 0625000	284591 618	286353 692	0 993847	3 98	-0 5		
14	8 00	0 0156250	538504 85	268375 737	2 006533	8 04	0 5		
15	10 0	0 0100000	691748 506	280304 528	2 467846	9 89	-1 1		
16	20 0	0 00250000	1354684 17	262186 595	5 166870	20 7	3 5		
17	40 0	0 000625000	2705010 201	266291 167	10 158092	40 7	1 8		
18	50 0	0 000400000	3327640 907	266073 142	12 506489	50 2	0 4		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:
 Slope = 0 249250098
 Intercept = 0 00212399812
 R-Squared = 0 9978

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)
 AAR - Concentration Found is Greater than 50 0 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 23
Serum, Concentration of Nicotine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	3716109 206	305968 832	12 145385	1	48 7		49 4		1 6
2	0 00	3609577 684	301202 34	11 983897	1	48 1				
3	0 00	3616018 335	289449 747	12 492733	1	50 1				
4	0 00	3831053 379	307632 398	12 453348	1	50 0				
5	0 00	3403525 263	274849 735	12 383222	1	49 7				
95	0 00	4430373 207	354457 57	12 499023	1	50 1				
96	0 00	4268661 554	350630 455	12 174246	1	48 8				
36	1 50	108652 549	306787 661	0 354162	1	1 41	-6 0	1 46	-2 7	4 4
68	1 50	123468 754	328724 694	0 375599	1	1 50	0 0			
44	8 00	548153 201	300520 623	1 824012	1	7 31	-8 6	7 41	-7 4	1 9
76	8 00	637773 627	340322 662	1 874026	1	7 51	-6 1			
27	37 5	486138 811	267215 664	1 819275	5	36 5	-2 7	36 5	-2 7	0 3
60	37 5	548927 278	301776 128	1 818988	5	36 4	-2 9			
84	37 5	672328 025	367681 103	1 828563	5	36 6	-2 4			
52	37 5	2961951 288	317552 98	9 327424	1	37 4	-0 3	38 8	3 5	4 9
93	37 5	3282789 944	328281 054	9 999937	1	40 1	6 9			

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)
AAR - Concentration Found is Greater than 50 0 (Highest Standard)

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 23
Serum, Concentration of Nicotine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
09	N/A	1 / Day 1 -0 0333h	21406 253	288711 388	*0 074144	5	*BLQ<(2 50)	21	05104620000657	AA97220-01 05104620000657 09 N/A Serum-1 1 / Day 1 - 0333h
09	N/A	1 / Day 1 -0 0333h	11936 333	260726 625	*0 045781	5	*BLQ<(2 50)	22	05104620000673	AA97220-01 05104620000673 09 N/A Serum-1 1 / Day 1 - 0333h
09	N/A	1 / Day 1 -0 0333h	15423 702	267398 146	*0 057681	5	*BLQ<(2 50)	23	05104620000689	AA97220-01 05104620000689 09 N/A Serum-1 1 / Day 1 - 0333h
09	N/A	1 / Day 1 -0 0333h	60849 234	276118 13	0 220374	1	0 876	20	05104620000705	AA97220-01 05104620000705 09 N/A Serum-1 1 / Day 1 - 0333h
09	N/A	2 / Day 1 0h	10597 975	269458 548	*0 039331	5	*BLQ<(2 50)	28	05104620000658	AA97220-01 05104620000658 09 N/A Serum-1 2 / Day 1 0h
09	N/A	2 / Day 1 0h	54630 435	295457 489	0 184901	1	0 733	29	05104620000658	AA97220-01 05104620000658 09 N/A Serum-1 2 / Day 1 0h
09	N/A	2 / Day 1 0h	18331 64	267869 795	*0 068435	5	*BLQ<(2 50)	26	05104620000674	AA97220-01 05104620000674 09 N/A Serum-1 2 / Day 1 0h
09	N/A	2 / Day 1 0h	14370 741	282197 415	*0 050924	5	*BLQ<(2 50)	25	05104620000690	AA97220-01 05104620000690 09 N/A Serum-1 2 / Day 1 0h
09	N/A	2 / Day 1 0h	10979 422	268047 514	*0 040961	5	*BLQ<(2 50)	24	05104620000706	AA97220-01 05104620000706 09 N/A Serum-1 2 / Day 1 0h
09	N/A	3 / Day 1 0 05h	34290 085	282625 587	*0 121327	5	*BLQ<(2 50)	30	05104620000659	AA97220-01 05104620000659 09 N/A Serum-1 3 / Day 1 05h
09	N/A	3 / Day 1 0 05h	19922 935	295507 794	*0 067419	5	*BLQ<(2 50)	31	05104620000675	AA97220-01 05104620000675 09 N/A Serum-1 3 / Day 1 05h
09	N/A	3 / Day 1 0 05h	20173 495	298837 524	*0 067507	5	*BLQ<(2 50)	32	05104620000691	AA97220-01 05104620000691 09 N/A Serum-1 3 / Day 1 05h
09	N/A	3 / Day 1 0 05h	101964 44	317140 608	*0 321512	5	*6 41	33	05104620000707	AA97220-01 05104620000707 09 N/A Serum-1 3 / Day 1 05h
09	N/A	4 / Day 1 0 0833h	25360 572	296750 832	*0 085461	5	*BLQ<(2 50)	37	05104620000660	AA97220-01 05104620000660 09 N/A Serum-1 4 / Day 1 0833h
09	N/A	4 / Day 1 0 0833h	22510 028	324866 735	*0 069290	5	*BLQ<(2 50)	34	05104620000676	AA97220-01 05104620000676 09 N/A Serum-1 4 / Day 1 0833h
09	N/A	4 / Day 1 0 0833h	20244 135	318230 227	*0 063615	5	*BLQ<(2 50)	38	05104620000692	AA97220-01 05104620000692 09 N/A Serum-1 4 / Day 1 0833h
09	N/A	4 / Day 1 0 0833h	142685 633	292770 34	*0 487364	5	*9 73	35	05104620000708	AA97220-01 05104620000708 09 N/A Serum-1 4 / Day 1 0833h
09	N/A	5 / Day 1 0 125h	38184 815	294708 238	*0 129568	5	*2 56	41	05104620000661	AA97220-01 05104620000661 09 N/A Serum-1 5 / Day 1 125h
09	N/A	5 / Day 1 0 125h	24941 471	284681 818	*0 087612	5	*BLQ<(2 50)	42	05104620000677	AA97220-01 05104620000677 09 N/A Serum-1 5 / Day 1 125h
09	N/A	5 / Day 1 0 125h	24317 381	291855 073	*0 083320	5	*BLQ<(2 50)	39	05104620000693	AA97220-01 05104620000693 09 N/A Serum-1 5 / Day 1 125h
09	N/A	5 / Day 1 0 125h	185828 888	310924 611	*0 597665	5	*11 9	40	05104620000709	AA97220-01 05104620000709 09 N/A Serum-1 5 / Day 1 125h
09	N/A	6 / Day 1 0 1667h	38593 898	295674 304	*0 130528	5	*2 58	46	05104620000662	AA97220-01 05104620000662 09 N/A Serum-1 6 / Day 1 1667h
09	N/A	6 / Day 1 0 1667h	29394 297	304685 361	*0 096474	5	*BLQ<(2 50)	47	05104620000678	AA97220-01 05104620000678 09 N/A Serum-1 6 / Day 1 1667h
09	N/A	6 / Day 1 0 1667h	22307 243	293767 07	*0 075935	5	*BLQ<(2 50)	45	05104620000694	AA97220-01 05104620000694 09 N/A Serum-1 6 / Day 1 1667h
09	N/A	6 / Day 1 0 1667h	150939 322	305044 01	*0 494812	5	*9 88	43	05104620000710	AA97220-01 05104620000710 09 N/A Serum-1 6 / Day 1 1667h
09	N/A	7 / Day 1 0 25h	57561 565	307819 185	*0 186998	5	*3 71	50	05104620000663	AA97220-01 05104620000663 09 N/A Serum-1 7 / Day 1 25h
09	N/A	7 / Day 1 0 25h	28527 733	317756 615	*0 089779	5	*BLQ<(2 50)	49	05104620000679	AA97220-01 05104620000679 09 N/A Serum-1 7 / Day 1 25h
09	N/A	7 / Day 1 0 25h	32956 76	301815 34	*0 109195	5	*BLQ<(2 50)	48	05104620000695	AA97220-01 05104620000695 09 N/A Serum-1 7 / Day 1 25h
09	N/A	7 / Day 1 0 25h	132632 947	295005 093	*0 449595	5	*8 98	51	05104620000711	AA97220-01 05104620000711 09 N/A Serum-1 7 / Day 1 25h
09	N/A	8 / Day 1 0 333h	54269 706	310871 937	*0 174573	5	*3 46	56	05104620000664	AA97220-01 05104620000664 09 N/A Serum-1 8 / Day 1 333h
09	N/A	8 / Day 1 0 333h	60231 474	328575 353	*0 183311	5	*3 63	53	05104620000680	AA97220-01 05104620000680 09 N/A Serum-1 8 / Day 1 333h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
09	N/A	8 / Day 1 0 333h	32826 039	342219 518	*0 095921	5	*BLQ<(2 50)	54	05104620000696	AA97220-01 05104620000696 09 N/A Serum-1 8 / Day 1 333h
09	N/A	8 / Day 1 0 333h	133182 758	310765 435	*0 428564	5	*8 55	55	05104620000712	AA97220-01 05104620000712 09 N/A Serum-1 8 / Day 1 333h
09	N/A	9 / Day 1 0 5h	46299 965	320057 7	*0 144661	5	*2 86	58	05104620000665	AA97220-01 05104620000665 09 N/A Serum-1 9 / Day 1 5h
09	N/A	9 / Day 1 0 5h	37631 814	308459 899	*0 121999	5	*BLQ<(2 50)	57	05104620000681	AA97220-01 05104620000681 09 N/A Serum-1 9 / Day 1 5h
09	N/A	9 / Day 1 0 5h	66192 315	319021 608	*0 207485	5	*4 12	59	05104620000697	AA97220-01 05104620000697 09 N/A Serum-1 9 / Day 1 5h
09	N/A	9 / Day 1 0 5h	102543 972	276674 865	*0 370630	5	*7 39	61	05104620000713	AA97220-01 05104620000713 09 N/A Serum-1 9 / Day 1 5h
09	N/A	10 / Day 1 0 75h	38419 233	311717 77	*0 123250	5	*BLQ<(2 50)	62	05104620000666	AA97220-01 05104620000666 09 N/A Serum-1 10 / Day 1 75h
09	N/A	10 / Day 1 0 75h	42122 795	302919 288	*0 139056	5	*2 75	63	05104620000682	AA97220-01 05104620000682 09 N/A Serum-1 10 / Day 1 75h
09	N/A	10 / Day 1 0 75h	61561 758	319476 254	*0 192696	5	*3 82	64	05104620000698	AA97220-01 05104620000698 09 N/A Serum-1 10 / Day 1 75h
09	N/A	10 / Day 1 0 75h	115311 956	344566 725	*0 334658	5	*6 67	65	05104620000714	AA97220-01 05104620000714 09 N/A Serum-1 10 / Day 1 75h
09	N/A	11 / Day 1 1h	41921 963	328815 518	*0 127494	5	*2 51	70	05104620000667	AA97220-01 05104620000667 09 N/A Serum-1 11 / Day 1 1h
09	N/A	11 / Day 1 1h	50156 914	359764 48	*0 139416	5	*2 75	66	05104620000683	AA97220-01 05104620000683 09 N/A Serum-1 11 / Day 1 1h
09	N/A	11 / Day 1 1h	58424 972	341552 492	*0 171057	5	*3 39	69	05104620000699	AA97220-01 05104620000699 09 N/A Serum-1 11 / Day 1 1h
09	N/A	11 / Day 1 1h	101949 969	342143 648	*0 297974	5	*5 93	67	05104620000715	AA97220-01 05104620000715 09 N/A Serum-1 11 / Day 1 1h
09	N/A	12 / Day 1 1 25h	38727 629	349976 987	*0 110658	5	*BLQ<(2 50)	74	05104620000668	AA97220-01 05104620000668 09 N/A Serum-1 12 / Day 1 1 25h
09	N/A	12 / Day 1 1 25h	39870 394	340024 813	*0 117257	5	*BLQ<(2 50)	72	05104620000684	AA97220-01 05104620000684 09 N/A Serum-1 12 / Day 1 1 25h
09	N/A	12 / Day 1 1 25h	51291 984	326649 852	*0 157024	5	*3 11	71	05104620000700	AA97220-01 05104620000700 09 N/A Serum-1 12 / Day 1 1 25h
09	N/A	12 / Day 1 1 25h	85403 127	373898 237	*0 228413	5	*4 54	73	05104620000716	AA97220-01 05104620000716 09 N/A Serum-1 12 / Day 1 1 25h
09	N/A	13 / Day 1 1 5h	36843 443	360883 479	*0 102092	5	*BLQ<(2 50)	77	05104620000669	AA97220-01 05104620000669 09 N/A Serum-1 13 / Day 1 1 5h
09	N/A	13 / Day 1 1 5h	44521 522	373792 965	*0 119107	5	*BLQ<(2 50)	78	05104620000685	AA97220-01 05104620000685 09 N/A Serum-1 13 / Day 1 1 5h
09	N/A	13 / Day 1 1 5h	52669 414	368502 796	*0 142928	5	*2 82	79	05104620000701	AA97220-01 05104620000701 09 N/A Serum-1 13 / Day 1 1 5h
09	N/A	13 / Day 1 1 5h	83737 141	336802 002	*0 248624	5	*4 94	75	05104620000717	AA97220-01 05104620000717 09 N/A Serum-1 13 / Day 1 1 5h
09	N/A	14 / Day 1 2h	35403 568	350630 847	*0 100971	5	*BLQ<(2 50)	82	05104620000670	AA97220-01 05104620000670 09 N/A Serum-1 14 / Day 1 2h
09	N/A	14 / Day 1 2h	39602 248	336520 908	*0 117681	5	*BLQ<(2 50)	83	05104620000686	AA97220-01 05104620000686 09 N/A Serum-1 14 / Day 1 2h
09	N/A	14 / Day 1 2h	48750 863	349269 638	*0 139579	5	*2 76	80	05104620000702	AA97220-01 05104620000702 09 N/A Serum-1 14 / Day 1 2h
09	N/A	14 / Day 1 2h	54636 133	352880 335	*0 154829	5	*3 06	81	05104620000718	AA97220-01 05104620000718 09 N/A Serum-1 14 / Day 1 2h
09	N/A	15 / Day 1 2 5h	30944 367	380341 937	*0 081359	5	*BLQ<(2 50)	88	05104620000671	AA97220-01 05104620000671 09 N/A Serum-1 15 / Day 1 2 5h
09	N/A	15 / Day 1 2 5h	31799 703	329710 29	*0 096447	5	*BLQ<(2 50)	85	05104620000687	AA97220-01 05104620000687 09 N/A Serum-1 15 / Day 1 2 5h
09	N/A	15 / Day 1 2 5h	53967 133	356489 49	*0 151385	5	*2 99	87	05104620000703	AA97220-01 05104620000703 09 N/A Serum-1 15 / Day 1 2 5h
09	N/A	15 / Day 1 2 5h	49037	365409 41	*0 134197	5	*2 65	86	05104620000719	AA97220-01 05104620000719 09 N/A Serum-1 15 / Day 1 2 5h
09	N/A	16 / Day 1 3h	23402 341	350018 895	*0 066860	5	*BLQ<(2 50)	91	05104620000672	AA97220-01 05104620000672 09 N/A Serum-1 16 / Day 1 3h
09	N/A	16 / Day 1 3h	35141 982	388921 192	*0 090358	5	*BLQ<(2 50)	92	05104620000688	AA97220-01 05104620000688 09 N/A Serum-1 16 / Day 1 3h
09	N/A	16 / Day 1 3h	32982 27	380403 25	*0 086703	5	*BLQ<(2 50)	89	05104620000704	AA97220-01 05104620000704 09 N/A Serum-1 16 / Day 1 3h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
09	N/A	16 / Day 1 3h	51482.878	396617.042	*0.129805	5	*2.56	90	05104620000720	AA97220-01 05104620000720 09 N/A Serum-1 16 / Day 1 3h

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0.500 (Lowest Standard)

AAR - Concentration Found is Greater than 50.0 (Highest Standard)

* - Sample Rejected

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 24
 Serum, Concentration of Nicotine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		0	340991 76	0 000000	0 00610		0 00610	0 0
9	0 00		0	335351 193	0 000000	0 00610			
10	0 500	4 00000	37750 232	308541 861	0 122350	0 495	-1 0		
11	1 00	1 00000	74802 463	297660 804	0 251301	1 01	1 0		
12	2 00	0 250000	146575 585	285655 021	0 513121	2 06	3 0		
13	4 00	0 0625000	271006 768	273184 847	0 992027	3 97	-0 8		
14	8 00	0 0156250	577116 252	301171 133	1 916240	7 67	-4 1		
15	10 0	0 0100000	716526 701	286892 6	2 497543	9 99	-0 1		
16	20 0	0 00250000	1470346 748	284971 453	5 159628	20 6	3 0		
17	40 0	0 000625000	2902747 267	283129 51	10 252366	41 0	2 5		
18	50 0	0 000400000	3427509 441	284264 147	12 057481	48 2	-3 6		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:

Slope = 0 250166952

Intercept = -0 00152576226

R-Squared = 0 9990

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)

AAR - Concentration Found is Greater than 50 0 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 24
 Serum, Concentration of Nicotine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	4236812 076	344098 48	12 312789	1	49 2		49 8		1 6
2	0 00	4327621 198	352231 878	12 286285	1	49 1				
3	0 00	4642057 001	379495 595	12 232176	1	48 9				
4	0 00	4249652 801	341786 05	12 433664	1	49 7				
5	0 00	4409408 932	350415 057	12 583389	1	50 3				
91	0 00	4304220 052	338685 162	12 708617	1	50 8				
92	0 00	4208751 01	331558 916	12 693825	1	50 7				
30	1 50	106634 63	302940 898	0 351998	1	1 41	-6 0	1 48	-1 3	6 2
63	1 50	119034 503	310767 69	0 383034	1	1 54	2 7			
41	8 00	610030 416	315482 528	1 933642	1	7 74	-3 3	7 69	-3 9	1 0
74	8 00	607790 881	318466 316	1 908493	1	7 63	-4 6			
52	37 5	3103041 033	317037 953	9 787601	1	39 1	4 3	38 8	3 5	1 1
89	37 5	2878278 323	298826 965	9 631923	1	38 5	2 7			

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)
 AAR - Concentration Found is Greater than 50 0 (Highest Standard)

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 24
Serum, Concentration of Nicotine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
09	N/A	1 / Day 1 - 0 0333h	70228 547	293605 69	0 239193	1	0 962	20	05104620000641	AA97220-01 05104620000641 09 N/A Serum-1 1 / Day 1 - 0333h
09	N/A	2 / Day 1 0h	75155 156	300724 52	0 249914	1	1 01	21	05104620000642	AA97220-01 05104620000642 09 N/A Serum-1 2 / Day 1 0h
09	N/A	3 / Day 1 0 05h	66888 763	278594 279	0 240094	1	0 966	22	05104620000643	AA97220-01 05104620000643 09 N/A Serum-1 3 / Day 1 05h
09	N/A	4 / Day 1 0 0833h	88138 88	346388 032	0 254451	1	1 02	23	05104620000644	AA97220-01 05104620000644 09 N/A Serum-1 4 / Day 1 0833h
09	N/A	5 / Day 1 0 125h	99186 504	270093 445	0 367230	1	1 47	24	05104620000645	AA97220-01 05104620000645 09 N/A Serum-1 5 / Day 1 125h
09	N/A	6 / Day 1 0 1667h	142158 151	314804 241	0 451576	1	1 81	25	05104620000646	AA97220-01 05104620000646 09 N/A Serum-1 6 / Day 1 1667h
09	N/A	7 / Day 1 0 25h	193343 018	315713 682	0 612400	1	2 45	26	05104620000647	AA97220-01 05104620000647 09 N/A Serum-1 7 / Day 1 25h
09	N/A	8 / Day 1 0 333h	172245 969	304943 903	0 564845	1	2 26	27	05104620000648	AA97220-01 05104620000648 09 N/A Serum-1 8 / Day 1 333h
09	N/A	9 / Day 1 0 5h	170634 009	322465 492	0 529154	1	2 12	28	05104620000649	AA97220-01 05104620000649 09 N/A Serum-1 9 / Day 1 5h
09	N/A	10 / Day 1 0 75h	231660 775	319032 891	0 726134	1	2 91	29	05104620000650	AA97220-01 05104620000650 09 N/A Serum-1 10 / Day 1 75h
09	N/A	11 / Day 1 1h	221371 438	322641 004	0 686123	1	2 75	31	05104620000651	AA97220-01 05104620000651 09 N/A Serum-1 11 / Day 1 1h
09	N/A	12 / Day 1 1 25h	224962 744	345837 043	0 650488	1	2 61	32	05104620000652	AA97220-01 05104620000652 09 N/A Serum-1 12 / Day 1 1 25h
09	N/A	13 / Day 1 1 5h	197998 54	317500 995	0 623615	1	2 50	33	05104620000653	AA97220-01 05104620000653 09 N/A Serum-1 13 / Day 1 1 5h
09	N/A	14 / Day 1 2h	180068 163	315408 208	0 570905	1	2 29	34	05104620000654	AA97220-01 05104620000654 09 N/A Serum-1 14 / Day 1 2h
09	N/A	15 / Day 1 2 5h	134918 972	272022 229	0 495985	1	1 99	35	05104620000655	AA97220-01 05104620000655 09 N/A Serum-1 15 / Day 1 2 5h
09	N/A	16 / Day 1 3h	137418 145	320922 013	0 428198	1	1 72	36	05104620000656	AA97220-01 05104620000656 09 N/A Serum-1 16 / Day 1 3h
10	N/A	1 / Day 1 - 0 0333h	235131 417	306468 885	0 767228	1	3 07	38	05104620000753	AA97220-01 05104620000753 10 N/A Serum-1 1 / Day 1 - 0333h
10	N/A	1 / Day 1 - 0 0333h	155876 281	324750 377	0 479988	1	1 92	39	05104620000769	AA97220-01 05104620000769 10 N/A Serum-1 1 / Day 1 - 0333h
10	N/A	1 / Day 1 - 0 0333h	74742 944	306596 57	0 243783	1	0 981	37	05104620000785	AA97220-01 05104620000785 10 N/A Serum-1 1 / Day 1 - 0333h
10	N/A	2 / Day 1 0h	285061 775	303427 905	0 939471	1	3 76	42	05104620000754	AA97220-01 05104620000754 10 N/A Serum-1 2 / Day 1 0h
10	N/A	2 / Day 1 0h	164482 252	300850 975	0 546723	1	2 19	40	05104620000770	AA97220-01 05104620000770 10 N/A Serum-1 2 / Day 1 0h
10	N/A	2 / Day 1 0h	66156 842	318149 253	0 207943	1	0 837	43	05104620000786	AA97220-01 05104620000786 10 N/A Serum-1 2 / Day 1 0h
10	N/A	3 / Day 1 0 05h	240042 656	310804 067	0 772328	1	3 09	44	05104620000755	AA97220-01 05104620000755 10 N/A Serum-1 3 / Day 1 05h
10	N/A	3 / Day 1 0 05h	152055 135	306932 937	0 495402	1	1 99	45	05104620000771	AA97220-01 05104620000771 10 N/A Serum-1 3 / Day 1 05h
10	N/A	3 / Day 1 0 05h	196845 21	297515 2	0 661631	1	2 65	46	05104620000787	AA97220-01 05104620000787 10 N/A Serum-1 3 / Day 1 05h
10	N/A	4 / Day 1 0 0833h	275148 279	333088 353	0 826052	1	3 31	48	05104620000756	AA97220-01 05104620000756 10 N/A Serum-1 4 / Day 1 0833h
10	N/A	4 / Day 1 0 0833h	179685 097	316126 89	0 568395	1	2 28	47	05104620000772	AA97220-01 05104620000772 10 N/A Serum-1 4 / Day 1 0833h
10	N/A	4 / Day 1 0 0833h	301358 918	351138 137	0 858235	1	3 44	49	05104620000788	AA97220-01 05104620000788 10 N/A Serum-1 4 / Day 1 0833h
10	N/A	5 / Day 1 0 125h	265329 943	328814 145	0 806930	1	3 23	53	05104620000757	AA97220-01 05104620000757 10 N/A Serum-1 5 / Day 1 125h
10	N/A	5 / Day 1 0 125h	216968 916	322675 195	0 672407	1	2 69	50	05104620000773	AA97220-01 05104620000773 10 N/A Serum-1 5 / Day 1 125h
10	N/A	5 / Day 1 0 125h	548118 853	305501 582	1 794160	1	7 18	51	05104620000789	AA97220-01 05104620000789 10 N/A Serum-1 5 / Day 1 125h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
10	N/A	6 / Day 1 0 1667h	286195 793	327983 65	0 872592	1	3 49	55	05104620000758	AA97220-01 05104620000758 10 N/A Serum- 1 6 / Day 1 1667h
10	N/A	6 / Day 1 0 1667h	229386 945	302097 245	0 759315	1	3 04	56	05104620000774	AA97220-01 05104620000774 10 N/A Serum- 1 6 / Day 1 1667h
10	N/A	6 / Day 1 0 1667h	529904 258	296201 972	1 788996	1	7 16	54	05104620000790	AA97220-01 05104620000790 10 N/A Serum- 1 6 / Day 1 1667h
10	N/A	7 / Day 1 0 25h	324257 688	337994 768	0 959357	1	3 84	57	05104620000759	AA97220-01 05104620000759 10 N/A Serum- 1 7 / Day 1 25h
10	N/A	7 / Day 1 0 25h	378504 457	320742 78	1 180087	1	4 72	58	05104620000775	AA97220-01 05104620000775 10 N/A Serum- 1 7 / Day 1 25h
10	N/A	7 / Day 1 0 25h	570686 113	322452 3	1 769831	1	7 08	59	05104620000791	AA97220-01 05104620000791 10 N/A Serum- 1 7 / Day 1 25h
10	N/A	8 / Day 1 0 333h	341176 9	342516 08	0 996090	1	3 99	60	05104620000760	AA97220-01 05104620000760 10 N/A Serum- 1 8 / Day 1 333h
10	N/A	8 / Day 1 0 333h	399199 502	299082 842	1 334746	1	5 34	61	05104620000776	AA97220-01 05104620000776 10 N/A Serum- 1 8 / Day 1 333h
10	N/A	8 / Day 1 0 333h	577635 908	306637 414	1 883775	1	7 54	62	05104620000792	AA97220-01 05104620000792 10 N/A Serum- 1 8 / Day 1 333h
10	N/A	9 / Day 1 0 5h	305819 192	326992 015	0 935250	1	3 74	65	05104620000761	AA97220-01 05104620000761 10 N/A Serum- 1 9 / Day 1 5h
10	N/A	9 / Day 1 0 5h	392800 377	293880 053	1 336601	1	5 35	66	05104620000777	AA97220-01 05104620000777 10 N/A Serum- 1 9 / Day 1 5h
10	N/A	9 / Day 1 0 5h	544736 663	300365 138	1 813582	1	7 26	64	05104620000793	AA97220-01 05104620000793 10 N/A Serum- 1 9 / Day 1 5h
10	N/A	10 / Day 1 0 75h	369845 264	303861 35	1 217151	1	4 87	67	05104620000762	AA97220-01 05104620000762 10 N/A Serum- 1 10 / Day 1 75h
10	N/A	10 / Day 1 0 75h	560339 855	331156 326	1 692071	1	6 77	69	05104620000778	AA97220-01 05104620000778 10 N/A Serum- 1 10 / Day 1 75h
10	N/A	10 / Day 1 0 75h	488959 734	321652 35	1 520150	1	6 08	68	05104620000794	AA97220-01 05104620000794 10 N/A Serum- 1 10 / Day 1 75h
10	N/A	11 / Day 1 1h	444403 611	336909 705	1 319059	1	5 28	71	05104620000763	AA97220-01 05104620000763 10 N/A Serum- 1 11 / Day 1 1h
10	N/A	11 / Day 1 1h	624566 545	336489 722	1 856124	1	7 43	72	05104620000779	AA97220-01 05104620000779 10 N/A Serum- 1 11 / Day 1 1h
10	N/A	11 / Day 1 1h	346286 468	284333 652	1 217888	1	4 87	70	05104620000795	AA97220-01 05104620000795 10 N/A Serum- 1 11 / Day 1 1h
10	N/A	12 / Day 1 1 25h	429443 346	323175 76	1 328823	1	5 32	76	05104620000764	AA97220-01 05104620000764 10 N/A Serum- 1 12 / Day 1 1 25h
10	N/A	12 / Day 1 1 25h	582810 253	359207 314	1 622490	1	6 49	73	05104620000780	AA97220-01 05104620000780 10 N/A Serum- 1 12 / Day 1 1 25h
10	N/A	12 / Day 1 1 25h	310620 164	316884 853	0 980230	1	3 92	75	05104620000796	AA97220-01 05104620000796 10 N/A Serum- 1 12 / Day 1 1 25h
10	N/A	13 / Day 1 1 5h	351665 256	301707 341	1 165584	1	4 67	79	05104620000765	AA97220-01 05104620000765 10 N/A Serum- 1 13 / Day 1 1 5h
10	N/A	13 / Day 1 1 5h	471800 046	321612 123	1 466985	1	5 87	77	05104620000781	AA97220-01 05104620000781 10 N/A Serum- 1 13 / Day 1 1 5h
10	N/A	13 / Day 1 1 5h	302910 226	322690 639	0 938702	1	3 76	78	05104620000797	AA97220-01 05104620000797 10 N/A Serum- 1 13 / Day 1 1 5h
10	N/A	14 / Day 1 2h	326583 58	320180 717	1 019998	1	4 08	80	05104620000766	AA97220-01 05104620000766 10 N/A Serum- 1 14 / Day 1 2h
10	N/A	14 / Day 1 2h	343391 931	306239 245	1 121319	1	4 49	81	05104620000782	AA97220-01 05104620000782 10 N/A Serum- 1 14 / Day 1 2h
10	N/A	14 / Day 1 2h	276841 81	320623 818	0 863447	1	3 46	82	05104620000798	AA97220-01 05104620000798 10 N/A Serum- 1 14 / Day 1 2h
10	N/A	15 / Day 1 2 5h	301905 889	329372 966	0 916608	1	3 67	85	05104620000767	AA97220-01 05104620000767 10 N/A Serum- 1 15 / Day 1 2 5h
10	N/A	15 / Day 1 2 5h	276669 482	324054 99	0 853773	1	3 42	83	05104620000783	AA97220-01 05104620000783 10 N/A Serum- 1 15 / Day 1 2 5h
10	N/A	15 / Day 1 2 5h	203391 248	303051 02	0 671145	1	2 69	84	05104620000799	AA97220-01 05104620000799 10 N/A Serum- 1 15 / Day 1 2 5h
10	N/A	16 / Day 1 3h	243476 887	322296 444	0 755444	1	3 03	88	05104620000768	AA97220-01 05104620000768 10 N/A Serum- 1 16 / Day 1 3h
10	N/A	16 / Day 1 3h	303727 519	331047 758	0 917473	1	3 67	87	05104620000784	AA97220-01 05104620000784 10 N/A Serum- 1 16 / Day 1 3h
10	N/A	16 / Day 1 3h	186105 873	325160 517	0 572351	1	2 29	86	05104620000800	AA97220-01 05104620000800 10 N/A Serum- 1 16 / Day 1 3h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0.500 (Lowest Standard)

AAR - Concentration Found is Greater than 50.0 (Highest Standard)

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 30
 Serum, Concentration of Nicotine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		0	194734 285	0 000000	0 0187		0 0187	0 0
9	0 00		0	184992 314	0 000000	0 0187			
10	0 500	4 00000	29246 834	241165 438	0 121273	0 508	1 6		
11	1 00	1 00000	55547 683	235200 617	0 236172	0 972	-2 8		
12	2 00	0 250000	93938 943	188962 637	0 497130	2 02	1 0		
13	4 00	0 0625000	227305 816	237533 405	0 956943	3 88	-3 0		
14	8 00	0 0156250	378834 222	200328 207	1 891068	7 65	-4 4		
15	10 0	0 0100000	503979 592	207406 628	2 429911	9 82	-1 8		
16	20 0	0 00250000	1063087 352	197493 117	5 382908	21 7	8 5		
17	40 0	0 000625000	2437717 327	242479 317	10 053300	40 6	1 5		
18	50 0	0 000400000	2508734 472	204742 38	12 253127	49 5	-1 0		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:
 Slope = 0 247809309
 Intercept = -0 00463144691
 R-Squared = 0 9979

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)
 AAR - Concentration Found is Greater than 50 0 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 30
Serum, Concentration of Nicotine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	2602008 858	211506 255	12 302279	1	49 7		49 0		1 9
2	0 00	2504493 088	208715 462	11 999557	1	48 4				
3	0 00	2550035 236	205168 91	12 428955	1	50 2				
4	0 00	2975135 002	251833 85	11 813880	1	47 7				
5	0 00	2958675 008	247471 815	11 955604	1	48 3				
91	0 00	2277357 704	186593 386	12 204922	1	49 3				
92	0 00	2664391 621	216504 072	12 306427	1	49 7				
30	1 50	70172 317	179934 863	0 389987	1	1 59	6 0	1 52	1 3	6 5
63	1 50	58351 083	164512 041	0 354692	1	1 45	-3 3			
41	8 00	304818 888	171358 993	1 778832	1	7 20	-10 0	7 50	-6 3	5 7
74	8 00	359053 41	186139 447	1 928949	1	7 80	-2 5			
52	37 5	1667185 37	175801 905	9 483318	1	38 3	2 1	37 8	0 8	2 1
89	37 5	2001086 803	217017 605	9 220850	1	37 2	-0 8			

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)
AAR - Concentration Found is Greater than 50 0 (Highest Standard)

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 30
Serum, Concentration of Nicotine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
13	N/A	1 / Day 1 -0 0333h	23338 397	198290 6	0 117698	1	BLQ<(0 500)	23	05104620000977	AA97220-01 05104620000977 13 N/A Serum-1 1 / Day 1 - 0333h
13	N/A	1 / Day 1 -0 0333h	48358 677	229052 654	0 211125	1	0 871	20	05104620000993	AA97220-01 05104620000993 13 N/A Serum-1 1 / Day 1 - 0333h
13	N/A	1 / Day 1 -0 0333h	58328 495	231271 405	0 252208	1	1 04	22	05104620001009	AA97220-01 05104620001009 13 N/A Serum-1 1 / Day 1 - 0333h
13	N/A	1 / Day 1 -0 0333h	25498 335	191851 27	0 132907	1	0 555	21	05104620001025	AA97220-01 05104620001025 13 N/A Serum-1 1 / Day 1 - 0333h
13	N/A	2 / Day 1 0h	29152 764	225068 412	0 129528	1	0 541	26	05104620000978	AA97220-01 05104620000978 13 N/A Serum-1 2 / Day 1 0h
13	N/A	2 / Day 1 0h	36889 638	208086 195	0 177281	1	0 734	25	05104620000994	AA97220-01 05104620000994 13 N/A Serum-1 2 / Day 1 0h
13	N/A	2 / Day 1 0h	45318 981	193665 958	0 234006	1	0 963	24	05104620001010	AA97220-01 05104620001010 13 N/A Serum-1 2 / Day 1 0h
13	N/A	2 / Day 1 0h	26463 185	166814 597	0 158638	1	0 659	27	05104620001026	AA97220-01 05104620001026 13 N/A Serum-1 2 / Day 1 0h
13	N/A	3 / Day 1 0 05h	31978 485	191317 65	0 167149	1	0 693	29	05104620000979	AA97220-01 05104620000979 13 N/A Serum-1 3 / Day 1 05h
13	N/A	3 / Day 1 0 05h	50923 185	224483 155	0 226846	1	0 934	32	05104620000995	AA97220-01 05104620000995 13 N/A Serum-1 3 / Day 1 05h
13	N/A	3 / Day 1 0 05h	49146 626	193524 174	0 253956	1	1 04	31	05104620001011	AA97220-01 05104620001011 13 N/A Serum-1 3 / Day 1 05h
13	N/A	3 / Day 1 0 05h	189898 912	183088 229	1 037199	1	4 20	28	05104620001027	AA97220-01 05104620001027 13 N/A Serum-1 3 / Day 1 05h
13	N/A	4 / Day 1 0 0833h	31277 333	181734 222	0 172105	1	0 713	33	05104620000980	AA97220-01 05104620000980 13 N/A Serum-1 4 / Day 1 0833h
13	N/A	4 / Day 1 0 0833h	79361 83	151035 272	0 525452	1	2 14	35	05104620000996	AA97220-01 05104620000996 13 N/A Serum-1 4 / Day 1 0833h
13	N/A	4 / Day 1 0 0833h	47322 09	186466 412	0 253783	1	1 04	36	05104620001012	AA97220-01 05104620001012 13 N/A Serum-1 4 / Day 1 0833h
13	N/A	4 / Day 1 0 0833h	247240 93	196993 033	1 255074	1	5 08	34	05104620001028	AA97220-01 05104620001028 13 N/A Serum-1 4 / Day 1 0833h
13	N/A	5 / Day 1 0 125h	32549 279	171493 638	0 189799	1	0 785	38	05104620000981	AA97220-01 05104620000981 13 N/A Serum-1 5 / Day 1 125h
13	N/A	5 / Day 1 0 125h	153240 041	197098 37	0 777480	1	3 16	39	05104620000997	AA97220-01 05104620000997 13 N/A Serum-1 5 / Day 1 125h
13	N/A	5 / Day 1 0 125h	69950 485	214470 249	0 326155	1	1 33	37	05104620001013	AA97220-01 05104620001013 13 N/A Serum-1 5 / Day 1 125h
13	N/A	5 / Day 1 0 125h	281245 147	193654 36	1 452305	1	5 88	40	05104620001029	AA97220-01 05104620001029 13 N/A Serum-1 5 / Day 1 125h
13	N/A	6 / Day 1 0 1667h	40069 433	199258 772	0 201092	1	0 830	42	05104620000982	AA97220-01 05104620000982 13 N/A Serum-1 6 / Day 1 1667h
13	N/A	6 / Day 1 0 1667h	147967 317	179509 13	0 824289	1	3 34	44	05104620000998	AA97220-01 05104620000998 13 N/A Serum-1 6 / Day 1 1667h
13	N/A	6 / Day 1 0 1667h	61268 232	169817 562	0 360789	1	1 47	45	05104620001014	AA97220-01 05104620001014 13 N/A Serum-1 6 / Day 1 1667h
13	N/A	6 / Day 1 0 1667h	0	0	*N/A	1	*BLQ<(0 500)	43	05104620001030	AA97220-01 05104620001030 13 N/A Serum-1 6 / Day 1 1667h
13	N/A	7 / Day 1 0 25h	87813 225	208774 735	0 420612	1	1 72	48	05104620000983	AA97220-01 05104620000983 13 N/A Serum-1 7 / Day 1 25h
13	N/A	7 / Day 1 0 25h	168781 555	192653 869	0 876087	1	3 55	49	05104620000999	AA97220-01 05104620000999 13 N/A Serum-1 7 / Day 1 25h
13	N/A	7 / Day 1 0 25h	76440 025	204704 052	0 373417	1	1 53	47	05104620001015	AA97220-01 05104620001015 13 N/A Serum-1 7 / Day 1 25h
13	N/A	7 / Day 1 0 25h	310555 018	175875 188	1 765769	1	7 14	46	05104620001031	AA97220-01 05104620001031 13 N/A Serum-1 7 / Day 1 25h
13	N/A	8 / Day 1 0 333h	37410 029	168788 672	0 221638	1	0 913	53	05104620000984	AA97220-01 05104620000984 13 N/A Serum-1 8 / Day 1 333h
13	N/A	8 / Day 1 0 333h	203377 922	215901 632	0 941993	1	3 82	51	05104620001000	AA97220-01 05104620001000 13 N/A Serum-1 8 / Day 1 333h
13	N/A	8 / Day 1 0 333h	72244 196	173009 067	0 417575	1	1 70	54	05104620001016	AA97220-01 05104620001016 13 N/A Serum-1 8 / Day 1 333h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
13	N/A	8 / Day 1 0 333h	384681 48	218757 358	1 758485	1	7 11	50	05104620001032	AA97220-01 05104620001032 13 N/A Serum-1 8 / Day 1 333h
13	N/A	9 / Day 1 0 5h	60142 708	194816 609	0 308714	1	1 26	57	05104620000985	AA97220-01 05104620000985 13 N/A Serum-1 9 / Day 1 5h
13	N/A	9 / Day 1 0 5h	197314 212	196190 044	1 005730	1	4 08	58	05104620001001	AA97220-01 05104620001001 13 N/A Serum-1 9 / Day 1 5h
13	N/A	9 / Day 1 0 5h	108571 51	190481 782	0 569984	1	2 32	56	05104620001017	AA97220-01 05104620001017 13 N/A Serum-1 9 / Day 1 5h
13	N/A	9 / Day 1 0 5h	270100 142	168186 298	1 605958	1	6 50	55	05104620001033	AA97220-01 05104620001033 13 N/A Serum-1 9 / Day 1 5h
13	N/A	10 / Day 1 0 75h	52605 733	170807 823	0 307982	1	1 26	59	05104620000986	AA97220-01 05104620000986 13 N/A Serum-1 10 / Day 1 75h
13	N/A	10 / Day 1 0 75h	154829 519	182900 293	0 846524	1	3 43	62	05104620001002	AA97220-01 05104620001002 13 N/A Serum-1 10 / Day 1 75h
13	N/A	10 / Day 1 0 75h	121633 814	196506 324	0 618982	1	2 52	61	05104620001018	AA97220-01 05104620001018 13 N/A Serum-1 10 / Day 1 75h
13	N/A	10 / Day 1 0 75h	178070 01	169723 672	1 049176	1	4 25	60	05104620001034	AA97220-01 05104620001034 13 N/A Serum-1 10 / Day 1 75h
13	N/A	11 / Day 1 1h	47528 805	173722 14	0 273591	1	1 12	67	05104620000987	AA97220-01 05104620000987 13 N/A Serum-1 11 / Day 1 1h
13	N/A	11 / Day 1 1h	110732 325	168200 813	0 658334	1	2 68	65	05104620001003	AA97220-01 05104620001003 13 N/A Serum-1 11 / Day 1 1h
13	N/A	11 / Day 1 1h	82627 465	176737 882	0 467514	1	1 91	66	05104620001019	AA97220-01 05104620001019 13 N/A Serum-1 11 / Day 1 1h
13	N/A	11 / Day 1 1h	148307 444	160147 629	0 926067	1	3 76	64	05104620001035	AA97220-01 05104620001035 13 N/A Serum-1 11 / Day 1 1h
13	N/A	12 / Day 1 1 25h	35191 642	156985 575	0 224171	1	0 923	69	05104620000988	AA97220-01 05104620000988 13 N/A Serum-1 12 / Day 1 1 25h
13	N/A	12 / Day 1 1 25h	104870 845	166443 375	0 630069	1	2 56	71	05104620001004	AA97220-01 05104620001004 13 N/A Serum-1 12 / Day 1 1 25h
13	N/A	12 / Day 1 1 25h	89139 325	185061 528	0 481674	1	1 96	70	05104620001020	AA97220-01 05104620001020 13 N/A Serum-1 12 / Day 1 1 25h
13	N/A	12 / Day 1 1 25h	122741 532	159623 783	0 768943	1	3 12	68	05104620001036	AA97220-01 05104620001036 13 N/A Serum-1 12 / Day 1 1 25h
13	N/A	13 / Day 1 1 5h	56493 14	234530 635	0 240877	1	0 991	73	05104620000989	AA97220-01 05104620000989 13 N/A Serum-1 13 / Day 1 1 5h
13	N/A	13 / Day 1 1 5h	95126 82	182389 607	0 521558	1	2 12	76	05104620001005	AA97220-01 05104620001005 13 N/A Serum-1 13 / Day 1 1 5h
13	N/A	13 / Day 1 1 5h	80979 155	203061 698	0 398791	1	1 63	72	05104620001021	AA97220-01 05104620001021 13 N/A Serum-1 13 / Day 1 1 5h
13	N/A	13 / Day 1 1 5h	142029 455	226277 961	0 627677	1	2 55	75	05104620001037	AA97220-01 05104620001037 13 N/A Serum-1 13 / Day 1 1 5h
13	N/A	14 / Day 1 2h	30202 093	160039 403	0 188717	1	0 780	78	05104620000990	AA97220-01 05104620000990 13 N/A Serum-1 14 / Day 1 2h
13	N/A	14 / Day 1 2h	92222 197	199504 172	0 462257	1	1 88	79	05104620001006	AA97220-01 05104620001006 13 N/A Serum-1 14 / Day 1 2h
13	N/A	14 / Day 1 2h	91981 825	238748 472	0 385267	1	1 57	77	05104620001022	AA97220-01 05104620001022 13 N/A Serum-1 14 / Day 1 2h
13	N/A	14 / Day 1 2h	111819 79	211943 905	0 527591	1	2 15	80	05104620001038	AA97220-01 05104620001038 13 N/A Serum-1 14 / Day 1 2h
13	N/A	15 / Day 1 2 5h	38606 382	200496 835	0 192554	1	0 796	83	05104620000991	AA97220-01 05104620000991 13 N/A Serum-1 15 / Day 1 2 5h
13	N/A	15 / Day 1 2 5h	75701 629	174563 49	0 433662	1	1 77	82	05104620001007	AA97220-01 05104620001007 13 N/A Serum-1 15 / Day 1 2 5h
13	N/A	15 / Day 1 2 5h	66264 105	211279 828	0 313632	1	1 28	81	05104620001023	AA97220-01 05104620001023 13 N/A Serum-1 15 / Day 1 2 5h
13	N/A	15 / Day 1 2 5h	106567 888	215387 807	0 494772	1	2 02	85	05104620001039	AA97220-01 05104620001039 13 N/A Serum-1 15 / Day 1 2 5h
13	N/A	16 / Day 1 3h	39971 43	188494 332	0 212056	1	0 874	86	05104620000992	AA97220-01 05104620000992 13 N/A Serum-1 16 / Day 1 3h
13	N/A	16 / Day 1 3h	65022 284	188688 338	0 344601	1	1 41	84	05104620001008	AA97220-01 05104620001008 13 N/A Serum-1 16 / Day 1 3h
13	N/A	16 / Day 1 3h	69505 004	215138 766	0 323071	1	1 32	87	05104620001024	AA97220-01 05104620001024 13 N/A Serum-1 16 / Day 1 3h
13	N/A	16 / Day 1 3h	73103 51	190389 682	0 383968	1	1 57	88	05104620001040	AA97220-01 05104620001040 13 N/A Serum-1 16 / Day 1 3h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0.500 (Lowest Standard)

AAR - Concentration Found is Greater than 50.0 (Highest Standard)

* - Sample Rejected

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 33
 Serum, Concentration of Nicotine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		1584 372	156032 881	0 010154	-0 0365		-0 0574	-51 6
9	0 00		0	154561 952	0 000000	-0 0783			
10	0 500	4 00000	24598 075	169397 692	0 145209	0 520	4 0		
11	1 00	1 00000	40007 462	163768 168	0 244293	0 929	-7 1		
12	2 00	0 250000	89022 876	178310 683	0 499257	1 98	-1 0		
13	4 00	0 0625000	196285 645	202091 814	0 971270	3 92	-2 0		
14	8 00	0 0156250	430532 664	225247 14	1 911379	7 80	-2 5		
15	10 0	0 0100000	445827 273	178418 125	2 498778	10 2	2 0		
16	20 0	0 00250000	1005689 866	205558 355	4 892479	20 1	0 5		
17	40 0	0 000625000	1837687 433	177548 311	10 350352	42 6	6 5		
18	50 0	0 000400000	2154722 145	178310 92	12 084073	49 7	-0 6		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:

Slope = 0 242628582

Intercept = 0 0190083910

R-Squared = 0 9979

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)

AAR - Concentration Found is Greater than 50 0 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 33
 Serum, Concentration of Nicotine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	2054989 12	165512 915	12 415884	1	51 1		49 6		2 6
2	0 00	1848679 901	152006 568	12 161842	1	50 0				
3	0 00	1875459 004	160411 348	11 691561	1	48 1				
4	0 00	1989172 897	161094 328	12 347877	1	50 8				
5	0 00	1932729 531	159222 278	12 138562	1	50 0				
95	0 00	2303471 572	198894 53	11 581372	1	47 7				
96	0 00	2417609 991	199921 867	12 092774	1	49 8				
35	1 50	79694 792	238941 381	0 333533	1	1 30	-13 3	1 29	-14 0	1 6
68	1 50	71599 189	218373 643	0 327875	1	1 27	-15 3			
43	8 00	431427 729	230494 788	1 871746	1	7 64	-4 5	7 50	-6 3	2 7
75	8 00	443953 218	246385 79	1 801862	1	7 35	-8 1			
27	37 5	433298 195	234851 983	1 844984	5	37 6	0 3	37 4	-0 3	2 1
60	37 5	386082 532	207346 393	1 862017	5	38 0	1 3			
83	37 5	316174 625	176406 557	1 792307	5	36 5	-2 7			
51	37 5	2016641 265	209586 17	9 622015	1	39 6	5 6	38 7	3 2	3 3
93	37 5	1818107 284	197637 355	9 199209	1	37 8	0 8			

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)
 AAR - Concentration Found is Greater than 50 0 (Highest Standard)

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 33
Serum, Concentration of Nicotine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
14	N/A	5 / Day 1 0 125h	21353 452	226338 692	*0 094343	5	*BLQ<(2 50)	39	05104620001077	AA97220-01 05104620001077 14 N/A Serum-1 5 / Day 1 125h
14	N/A	5 / Day 1 0 125h	88209 015	222213 159	*0 396957	5	*7 79	38	05104620001109	AA97220-01 05104620001109 14 N/A Serum-1 5 / Day 1 125h
14	N/A	6 / Day 1 0 1667h	28594 995	196073 843	*0 145838	5	*2 61	40	05104620001078	AA97220-01 05104620001078 14 N/A Serum-1 6 / Day 1 1667h
14	N/A	6 / Day 1 0 1667h	22096 457	211194 443	*0 104626	5	*BLQ<(2 50)	42	05104620001094	AA97220-01 05104620001094 14 N/A Serum-1 6 / Day 1 1667h
14	N/A	6 / Day 1 0 1667h	109120 928	207753 053	*0 525243	5	*10 4	41	05104620001110	AA97220-01 05104620001110 14 N/A Serum-1 6 / Day 1 1667h
14	N/A	7 / Day 1 0 25h	31213 896	209312 072	*0 149126	5	*2 68	45	05104620001079	AA97220-01 05104620001079 14 N/A Serum-1 7 / Day 1 25h
14	N/A	7 / Day 1 0 25h	36563 128	225308 938	*0 162280	5	*2 95	46	05104620001095	AA97220-01 05104620001095 14 N/A Serum-1 7 / Day 1 25h
14	N/A	7 / Day 1 0 25h	94192 59	179482 911	*0 524800	5	*10 4	44	05104620001111	AA97220-01 05104620001111 14 N/A Serum-1 7 / Day 1 25h
14	N/A	8 / Day 1 0 333h	27328 894	233461 597	*0 117059	5	*BLQ<(2 50)	47	05104620001080	AA97220-01 05104620001080 14 N/A Serum-1 8 / Day 1 333h
14	N/A	8 / Day 1 0 333h	33843 988	203875 889	*0 166003	5	*3 03	48	05104620001096	AA97220-01 05104620001096 14 N/A Serum-1 8 / Day 1 333h
14	N/A	8 / Day 1 0 333h	99824 052	215138 107	*0 464000	5	*9 17	49	05104620001112	AA97220-01 05104620001112 14 N/A Serum-1 8 / Day 1 333h
14	N/A	9 / Day 1 0 5h	30285 338	201425 63	*0 150355	5	*2 71	50	05104620001081	AA97220-01 05104620001081 14 N/A Serum-1 9 / Day 1 5h
14	N/A	9 / Day 1 0 5h	34780 895	206287 343	*0 168604	5	*3 08	53	05104620001097	AA97220-01 05104620001097 14 N/A Serum-1 9 / Day 1 5h
14	N/A	9 / Day 1 0 5h	103970 355	216593 641	*0 480025	5	*9 50	52	05104620001113	AA97220-01 05104620001113 14 N/A Serum-1 9 / Day 1 5h
14	N/A	10 / Day 1 0 75h	30489 707	222623 739	*0 136956	5	*BLQ<(2 50)	55	05104620001082	AA97220-01 05104620001082 14 N/A Serum-1 10 / Day 1 75h
14	N/A	10 / Day 1 0 75h	42036 819	214592 165	*0 195892	5	*3 65	56	05104620001098	AA97220-01 05104620001098 14 N/A Serum-1 10 / Day 1 75h
14	N/A	10 / Day 1 0 75h	94519 56	216616 595	*0 436345	5	*8 60	54	05104620001114	AA97220-01 05104620001114 14 N/A Serum-1 10 / Day 1 75h
14	N/A	11 / Day 1 1h	27539 283	199410 769	*0 138103	5	*BLQ<(2 50)	59	05104620001083	AA97220-01 05104620001083 14 N/A Serum-1 11 / Day 1 1h
14	N/A	11 / Day 1 1h	29358 59	200008 291	*0 146787	5	*2 63	57	05104620001099	AA97220-01 05104620001099 14 N/A Serum-1 11 / Day 1 1h
14	N/A	11 / Day 1 1h	79621 965	221722 317	*0 359107	5	*7 01	58	05104620001115	AA97220-01 05104620001115 14 N/A Serum-1 11 / Day 1 1h
14	N/A	12 / Day 1 1 25h	20715 267	204524 352	*0 101285	5	*BLQ<(2 50)	62	05104620001084	AA97220-01 05104620001084 14 N/A Serum-1 12 / Day 1 1 25h
14	N/A	12 / Day 1 1 25h	74101 022	205235 44	*0 361054	5	*7 05	61	05104620001116	AA97220-01 05104620001116 14 N/A Serum-1 12 / Day 1 1 25h
14	N/A	13 / Day 1 1 5h	30909 747	219179 205	*0 141025	5	*2 51	65	05104620001085	AA97220-01 05104620001085 14 N/A Serum-1 13 / Day 1 1 5h
14	N/A	13 / Day 1 1 5h	25250 002	197449 579	*0 127881	5	*BLQ<(2 50)	63	05104620001101	AA97220-01 05104620001101 14 N/A Serum-1 13 / Day 1 1 5h
14	N/A	13 / Day 1 1 5h	67250 448	209575 132	*0 320889	5	*6 22	64	05104620001117	AA97220-01 05104620001117 14 N/A Serum-1 13 / Day 1 1 5h
14	N/A	14 / Day 1 2h	25177 225	250918 341	*0 100340	5	*BLQ<(2 50)	67	05104620001086	AA97220-01 05104620001086 14 N/A Serum-1 14 / Day 1 2h
14	N/A	14 / Day 1 2h	21340 628	186112 363	*0 114665	5	*BLQ<(2 50)	69	05104620001102	AA97220-01 05104620001102 14 N/A Serum-1 14 / Day 1 2h
14	N/A	14 / Day 1 2h	86540 645	245544 626	*0 352444	5	*6 87	66	05104620001118	AA97220-01 05104620001118 14 N/A Serum-1 14 / Day 1 2h
14	N/A	15 / Day 1 2 5h	19825 51	235827 19	*0 084068	5	*BLQ<(2 50)	72	05104620001087	AA97220-01 05104620001087 14 N/A Serum-1 15 / Day 1 2 5h
14	N/A	15 / Day 1 2 5h	21356 665	219641 543	*0 097234	5	*BLQ<(2 50)	71	05104620001103	AA97220-01 05104620001103 14 N/A Serum-1 15 / Day 1 2 5h
14	N/A	15 / Day 1 2 5h	51511 572	197380 974	*0 260975	5	*4 99	70	05104620001119	AA97220-01 05104620001119 14 N/A Serum-1 15 / Day 1 2 5h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
14	N/A	16 / Day 1 3h	15302 62	212189 918	*0 072118	5	*BLQ<(2 50)	76	05104620001088	AA97220-01 05104620001088 14 N/A Serum-1 16 / Day 1 3h
14	N/A	16 / Day 1 3h	17946 96	207967 837	*0 086297	5	*BLQ<(2 50)	73	05104620001104	AA97220-01 05104620001104 14 N/A Serum-1 16 / Day 1 3h
14	N/A	16 / Day 1 3h	51938 533	239639 267	*0 216736	5	*4 07	74	05104620001120	AA97220-01 05104620001120 14 N/A Serum-1 16 / Day 1 3h
15	N/A	1 / Day 1 -0 0333h	9637 542	207072 097	*0 046542	5	*BLQ<(2 50)	77	05104620001137	AA97220-01 05104620001137 15 N/A Serum-1 1 / Day 1 - 0333h
15	N/A	4 / Day 1 0 0833h	34037 629	236743 937	*0 143774	5	*2 57	78	05104620001124	AA97220-01 05104620001124 15 N/A Serum-1 4 / Day 1 0833h
15	N/A	7 / Day 1 0 25h	40702 833	206772 052	*0 196849	5	*3 66	79	05104620001127	AA97220-01 05104620001127 15 N/A Serum-1 7 / Day 1 25h
15	N/A	8 / Day 1 0 333h	60571 403	215895 6	*0 280559	5	*5 39	80	05104620001128	AA97220-01 05104620001128 15 N/A Serum-1 8 / Day 1 333h
15	N/A	10 / Day 1 0 75h	56432 934	186904 913	*0 301934	5	*5 83	82	05104620001130	AA97220-01 05104620001130 15 N/A Serum-1 10 / Day 1 75h
15	N/A	10 / Day 1 0 75h	39329 968	245333 602	*0 160312	5	*2 91	81	05104620001162	AA97220-01 05104620001162 15 N/A Serum-1 10 / Day 1 75h
15	N/A	11 / Day 1 1h	61995 831	180151 32	*0 344132	5	*6 70	84	05104620001131	AA97220-01 05104620001131 15 N/A Serum-1 11 / Day 1 1h
15	N/A	11 / Day 1 1h	29559 995	183530 234	*0 161063	5	*2 93	85	05104620001147	AA97220-01 05104620001147 15 N/A Serum-1 11 / Day 1 1h
15	N/A	12 / Day 1 1 25h	48118 666	181543 857	*0 265053	5	*5 07	86	05104620001132	AA97220-01 05104620001132 15 N/A Serum-1 12 / Day 1 1 25h
15	N/A	14 / Day 1 2h	55485 668	213029 742	*0 260460	5	*4 98	88	05104620001134	AA97220-01 05104620001134 15 N/A Serum-1 14 / Day 1 2h
15	N/A	14 / Day 1 2h	26995 169	203288 253	*0 132793	5	*BLQ<(2 50)	87	05104620001166	AA97220-01 05104620001166 15 N/A Serum-1 14 / Day 1 2h
16	N/A	2 / Day 1 0h	75204 24	233781 31	0 321686	1	1 25	89	05104620001266	AA97220-01 05104620001266 16 N/A Serum-1 2 / Day 1 0h
16	N/A	3 / Day 1 0 05h	136890 857	181427 443	0 754521	5	15 2	90	05104620001267	AA97220-01 05104620001267 16 N/A Serum-1 3 / Day 1 05h
16	N/A	9 / Day 1 0 5h	69129 447	169769 432	*0 407196	5	*8 00	91	05104620001273	AA97220-01 05104620001273 16 N/A Serum-1 9 / Day 1 5h
16	N/A	13 / Day 1 1 5h	45208 112	184221 81	*0 245400	5	*4 67	92	05104620001277	AA97220-01 05104620001277 16 N/A Serum-1 13 / Day 1 1 5h
17	N/A	1 / Day 1 -0 0333h	56620 47	240881 886	0 235055	1	0 890	20	05104620001281	AA97220-01 05104620001281 17 N/A Serum-1 1 / Day 1 - 0333h
17	N/A	2 / Day 1 0h	48361 311	186366 085	0 259496	1	0 991	21	05104620001282	AA97220-01 05104620001282 17 N/A Serum-1 2 / Day 1 0h
17	N/A	3 / Day 1 0 05h	49806 562	236781 998	0 210348	1	0 789	22	05104620001283	AA97220-01 05104620001283 17 N/A Serum-1 3 / Day 1 05h
17	N/A	4 / Day 1 0 0833h	50641 255	233895 453	0 216512	1	0 814	23	05104620001284	AA97220-01 05104620001284 17 N/A Serum-1 4 / Day 1 0833h
17	N/A	5 / Day 1 0 125h	53980 825	199552 345	0 270510	1	1 04	24	05104620001285	AA97220-01 05104620001285 17 N/A Serum-1 5 / Day 1 125h
17	N/A	6 / Day 1 0 1667h	69664 38	240095 443	0 290153	1	1 12	25	05104620001286	AA97220-01 05104620001286 17 N/A Serum-1 6 / Day 1 1667h
17	N/A	7 / Day 1 0 25h	76020 786	198959 313	0 382092	1	1 50	26	05104620001287	AA97220-01 05104620001287 17 N/A Serum-1 7 / Day 1 25h
17	N/A	8 / Day 1 0 333h	175845 076	233212 28	0 754013	1	3 03	28	05104620001288	AA97220-01 05104620001288 17 N/A Serum-1 8 / Day 1 333h
17	N/A	9 / Day 1 0 5h	234749 777	207375 303	1 132005	1	4 59	29	05104620001289	AA97220-01 05104620001289 17 N/A Serum-1 9 / Day 1 5h
17	N/A	10 / Day 1 0 75h	159890 191	183666 598	0 870546	1	3 51	30	05104620001290	AA97220-01 05104620001290 17 N/A Serum-1 10 / Day 1 75h
17	N/A	11 / Day 1 1h	136254 437	179962 819	0 757125	1	3 04	31	05104620001291	AA97220-01 05104620001291 17 N/A Serum-1 11 / Day 1 1h
17	N/A	12 / Day 1 1 25h	109266 843	189899 488	0 575393	1	2 29	32	05104620001292	AA97220-01 05104620001292 17 N/A Serum-1 12 / Day 1 1 25h
17	N/A	13 / Day 1 1 5h	119856 879	236529 039	0 506732	1	2 01	33	05104620001293	AA97220-01 05104620001293 17 N/A Serum-1 13 / Day 1 1 5h
17	N/A	14 / Day 1 2h	79112 31	184983 507	0 427672	1	1 68	34	05104620001294	AA97220-01 05104620001294 17 N/A Serum-1 14 / Day 1 2h
17	N/A	15 / Day 1 2 5h	85802 929	224990 307	0 381363	1	1 49	36	05104620001295	AA97220-01 05104620001295 17 N/A Serum-1 15 / Day 1 2 5h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
17	N/A	16 / Day 1 3h	80752 017	197886 343	0 408073	1	1 60	37	05104620001296	AA97220-01 05104620001296 17 N/A Serum-1 16 / Day 1 3h

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)

AAR - Concentration Found is Greater than 50 0 (Highest Standard)

* - Sample Rejected

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 37
 Serum, Concentration of Nicotine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		0	148434 492	0 000000	-0 0437		-0 0437	0 0
9	0 00		0	159513 669	0 000000	-0 0437			
10	0 500	4 00000	19991 76	152117 185	0 131423	0 483	-3 4		
11	1 00	1 00000	41764 688	151140 29	0 276331	1 06	6 0		
12	2 00	0 250000	80382 682	155627 014	0 516509	2 03	1 5		
13	4 00	0 0625000	155604 506	153714 608	1 012295	4 02	0 5		
14	8 00	0 0156250	303118 172	155664 672	1 947251	7 77	-2 9		
15	10 0	0 0100000	419310 513	172419 943	2 431914	9 71	-2 9		
16	20 0	0 00250000	900898 843	181286 255	4 969482	19 9	-0 5		
17	40 0	0 000625000	1969296 848	192423 402	10 234186	41 0	2 5		
18	50 0	0 000400000	2258803 797	183064 892	12 338815	49 4	-1 2		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:

Slope = 0 249318880

Intercept = 0 0108938964

R-Squared = 0 9987

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)

AAR - Concentration Found is Greater than 50 0 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 37
 Serum, Concentration of Nicotine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	2166723 805	181658 602	11 927450	1	47 8		49 2		1 9
2	0 00	2193489 67	181885 9	12 059702	1	48 3				
3	0 00	2411294 974	193002 907	12 493568	1	50 1				
4	0 00	2130001 296	171106 385	12 448403	1	49 9				
5	0 00	2012007 85	161627 079	12 448458	1	49 9				
93	0 00	2065771 36	166880 663	12 378734	1	49 6				
94	0 00	2233555 001	184101 662	12 132183	1	48 6				
35	1 50	58776 202	177712 197	0 330738	1	1 28	-14 7	1 34	-10 7	6 3
67	1 50	58286 073	161799 963	0 360235	1	1 40	-6 7			
43	8 00	309000 846	169145 5	1 826835	1	7 28	-9 0	7 35	-8 1	1 3
75	8 00	332340 792	178693 968	1 859832	1	7 42	-7 3			
27	37 5	324419 909	178980 01	1 812604	5	36 1	-3 7	36 6	-2 4	2 1
59	37 5	288415 412	153515 828	1 878734	5	37 5	0 0			
83	37 5	249588 441	136975 093	1 822145	5	36 3	-3 2			
51	37 5	1620138 711	176178 075	9 196029	1	36 8	-1 9	36 6	-2 4	0 8
91	37 5	1302814 244	143419 057	9 083969	1	36 4	-2 9			

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)
 AAR - Concentration Found is Greater than 50 0 (Highest Standard)

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 37
Serum, Concentration of Nicotine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
03	N/A	1 / Day 1 -0 0333h	16941 843	154831 963	*0 109421	5	*BLQ<(2 50)	20	05104620000161	AA97220-01 05104620000161 03 N/A Serum-1 1 / Day 1 - 0333h
03	N/A	1 / Day 1 -0 0333h	20106 232	170010 425	*0 118265	5	*BLQ<(2 50)	21	05104620000177	AA97220-01 05104620000177 03 N/A Serum-1 1 / Day 1 - 0333h
03	N/A	1 / Day 1 -0 0333h	25435 401	185363 574	*0 137219	5	*2 53	22	05104620000193	AA97220-01 05104620000193 03 N/A Serum-1 1 / Day 1 - 0333h
03	N/A	2 / Day 1 0h	18277 717	181735 155	*0 100573	5	*BLQ<(2 50)	23	05104620000162	AA97220-01 05104620000162 03 N/A Serum-1 2 / Day 1 0h
03	N/A	2 / Day 1 0h	26494 063	186637 686	*0 141955	5	*2 63	24	05104620000178	AA97220-01 05104620000178 03 N/A Serum-1 2 / Day 1 0h
03	N/A	2 / Day 1 0h	19338 977	188127 013	*0 102797	5	*BLQ<(2 50)	25	05104620000194	AA97220-01 05104620000194 03 N/A Serum-1 2 / Day 1 0h
03	N/A	3 / Day 1 0 05h	19777 629	179807 953	*0 109993	5	*BLQ<(2 50)	26	05104620000163	AA97220-01 05104620000163 03 N/A Serum-1 3 / Day 1 05h
03	N/A	3 / Day 1 0 05h	34685 596	175644 965	*0 197476	5	*3 74	29	05104620000179	AA97220-01 05104620000179 03 N/A Serum-1 3 / Day 1 05h
03	N/A	3 / Day 1 0 05h	25916 512	161756 58	*0 160219	5	*2 99	28	05104620000195	AA97220-01 05104620000195 03 N/A Serum-1 3 / Day 1 05h
03	N/A	4 / Day 1 0 0833h	16278 593	167611 173	*0 097121	5	*BLQ<(2 50)	32	05104620000164	AA97220-01 05104620000164 03 N/A Serum-1 4 / Day 1 0833h
03	N/A	4 / Day 1 0 0833h	24100 005	181869 218	*0 132513	5	*BLQ<(2 50)	31	05104620000180	AA97220-01 05104620000180 03 N/A Serum-1 4 / Day 1 0833h
03	N/A	4 / Day 1 0 0833h	28775 812	169845 839	*0 169423	5	*3 18	30	05104620000196	AA97220-01 05104620000196 03 N/A Serum-1 4 / Day 1 0833h
03	N/A	5 / Day 1 0 125h	29408 13	179950 559	*0 163423	5	*3 06	36	05104620000165	AA97220-01 05104620000165 03 N/A Serum-1 5 / Day 1 125h
03	N/A	5 / Day 1 0 125h	26708 308	177532 019	*0 150442	5	*2 80	34	05104620000181	AA97220-01 05104620000181 03 N/A Serum-1 5 / Day 1 125h
03	N/A	5 / Day 1 0 125h	21369 643	159041 024	*0 134366	5	*BLQ<(2 50)	33	05104620000197	AA97220-01 05104620000197 03 N/A Serum-1 5 / Day 1 125h
03	N/A	6 / Day 1 0 1667h	24102 808	197025 293	*0 122334	5	*BLQ<(2 50)	37	05104620000166	AA97220-01 05104620000166 03 N/A Serum-1 6 / Day 1 1667h
03	N/A	6 / Day 1 0 1667h	35769 928	191460 995	*0 186826	5	*3 53	39	05104620000182	AA97220-01 05104620000182 03 N/A Serum-1 6 / Day 1 1667h
03	N/A	6 / Day 1 0 1667h	26047 615	183899 304	*0 141641	5	*2 62	38	05104620000198	AA97220-01 05104620000198 03 N/A Serum-1 6 / Day 1 1667h
03	N/A	7 / Day 1 0 25h	34598 865	170558 611	*0 202856	5	*3 85	40	05104620000167	AA97220-01 05104620000167 03 N/A Serum-1 7 / Day 1 25h
03	N/A	7 / Day 1 0 25h	38123 11	177294 457	*0 215027	5	*4 09	41	05104620000183	AA97220-01 05104620000183 03 N/A Serum-1 7 / Day 1 25h
03	N/A	7 / Day 1 0 25h	31523 386	181956 933	*0 173246	5	*3 26	42	05104620000199	AA97220-01 05104620000199 03 N/A Serum-1 7 / Day 1 25h
03	N/A	8 / Day 1 0 333h	25771 005	171509 868	*0 150260	5	*2 79	45	05104620000168	AA97220-01 05104620000168 03 N/A Serum-1 8 / Day 1 333h
03	N/A	8 / Day 1 0 333h	34612 265	182201 195	*0 189967	5	*3 59	44	05104620000184	AA97220-01 05104620000184 03 N/A Serum-1 8 / Day 1 333h
03	N/A	8 / Day 1 0 333h	40312 308	190427 433	*0 211694	5	*4 03	46	05104620000200	AA97220-01 05104620000200 03 N/A Serum-1 8 / Day 1 333h
03	N/A	9 / Day 1 0 5h	37231 347	204005 266	*0 182502	5	*3 44	49	05104620000169	AA97220-01 05104620000169 03 N/A Serum-1 9 / Day 1 5h
03	N/A	9 / Day 1 0 5h	37013 012	175226 843	*0 211229	5	*4 02	48	05104620000185	AA97220-01 05104620000185 03 N/A Serum-1 9 / Day 1 5h
03	N/A	9 / Day 1 0 5h	47383 676	203771 482	*0 232533	5	*4 44	47	05104620000201	AA97220-01 05104620000201 03 N/A Serum-1 9 / Day 1 5h
03	N/A	10 / Day 1 0 75h	38222 787	185430 293	*0 206130	5	*3 92	52	05104620000170	AA97220-01 05104620000170 03 N/A Serum-1 10 / Day 1 75h
03	N/A	10 / Day 1 0 75h	41675 732	188917 035	*0 220603	5	*4 21	53	05104620000186	AA97220-01 05104620000186 03 N/A Serum-1 10 / Day 1 75h
03	N/A	10 / Day 1 0 75h	44689 532	175383 362	*0 254811	5	*4 89	50	05104620000202	AA97220-01 05104620000202 03 N/A Serum-1 10 / Day 1 75h
03	N/A	11 / Day 1 1h	31888 502	172243 378	*0 185136	5	*3 49	55	05104620000171	AA97220-01 05104620000171 03 N/A Serum-1 11 / Day 1 1h
03	N/A	11 / Day 1 1h	37825 213	177808 017	*0 212731	5	*4 05	56	05104620000187	AA97220-01 05104620000187 03 N/A Serum-1 11 / Day 1 1h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
03	N/A	11 / Day 1 1h	53950 15	192541 8	*0 280200	5	*5 40	54	05104620000203	AA97220-01 05104620000203 03 N/A Serum-1 11 / Day 1 1h
03	N/A	12 / Day 1 1 25h	28679 668	161724 553	*0 177337	5	*3 34	58	05104620000172	AA97220-01 05104620000172 03 N/A Serum-1 12 / Day 1 1 25h
03	N/A	12 / Day 1 1 25h	35799 132	155914 32	*0 229608	5	*4 39	60	05104620000188	AA97220-01 05104620000188 03 N/A Serum-1 12 / Day 1 1 25h
03	N/A	12 / Day 1 1 25h	39413 412	166936 944	*0 236098	5	*4 52	57	05104620000204	AA97220-01 05104620000204 03 N/A Serum-1 12 / Day 1 1 25h
03	N/A	13 / Day 1 1 5h	28905 635	145580 972	*0 198554	5	*3 76	63	05104620000173	AA97220-01 05104620000173 03 N/A Serum-1 13 / Day 1 1 5h
03	N/A	13 / Day 1 1 5h	23301 407	130298 282	*0 178831	5	*3 37	61	05104620000189	AA97220-01 05104620000189 03 N/A Serum-1 13 / Day 1 1 5h
03	N/A	13 / Day 1 1 5h	35492 495	144389 38	*0 245811	5	*4 71	62	05104620000205	AA97220-01 05104620000205 03 N/A Serum-1 13 / Day 1 1 5h
03	N/A	14 / Day 1 2h	24965 439	150592 111	*0 165782	5	*3 11	64	05104620000174	AA97220-01 05104620000174 03 N/A Serum-1 14 / Day 1 2h
03	N/A	14 / Day 1 2h	30660 415	156490 313	*0 195925	5	*3 71	66	05104620000190	AA97220-01 05104620000190 03 N/A Serum-1 14 / Day 1 2h
03	N/A	14 / Day 1 2h	36614 997	157605 03	*0 232321	5	*4 44	65	05104620000206	AA97220-01 05104620000206 03 N/A Serum-1 14 / Day 1 2h
03	N/A	15 / Day 1 2 5h	30311 793	163044 56	*0 185911	5	*3 51	68	05104620000175	AA97220-01 05104620000175 03 N/A Serum-1 15 / Day 1 2 5h
03	N/A	15 / Day 1 2 5h	30225 555	163714 097	*0 184624	5	*3 48	69	05104620000191	AA97220-01 05104620000191 03 N/A Serum-1 15 / Day 1 2 5h
03	N/A	15 / Day 1 2 5h	38975 21	171204 208	*0 227653	5	*4 35	70	05104620000207	AA97220-01 05104620000207 03 N/A Serum-1 15 / Day 1 2 5h
03	N/A	16 / Day 1 3h	24419 242	144637 88	*0 168830	5	*3 17	71	05104620000176	AA97220-01 05104620000176 03 N/A Serum-1 16 / Day 1 3h
03	N/A	16 / Day 1 3h	22738 529	148044 663	*0 153592	5	*2 86	73	05104620000192	AA97220-01 05104620000192 03 N/A Serum-1 16 / Day 1 3h
03	N/A	16 / Day 1 3h	25197 303	137578 74	*0 183148	5	*3 45	72	05104620000208	AA97220-01 05104620000208 03 N/A Serum-1 16 / Day 1 3h
04	N/A	10 / Day 1 0 75h	45873 07	136108 075	0 337034	5	6 54	74	05104620000314	AA97220-01 05104620000314 04 N/A Serum-1 10 / Day 1 75h
13	N/A	11 / Day 1 1h	60876 503	142565 653	0 427007	1	1 67	76	05104620000971	AA97220-01 05104620000971 13 N/A Serum-1 11 / Day 1 1h
14	N/A	1 / Day 1 -0 0333h	10468 138	160479 162	*0 065231	5	*BLQ<(2 50)	78	05104620001073	AA97220-01 05104620001073 14 N/A Serum-1 1 / Day 1 - 0333h
14	N/A	1 / Day 1 -0 0333h	6956 347	162389 663	*0 042837	5	*BLQ<(2 50)	79	05104620001089	AA97220-01 05104620001089 14 N/A Serum-1 1 / Day 1 - 0333h
14	N/A	1 / Day 1 -0 0333h	9012 121	160923 133	*0 056003	5	*BLQ<(2 50)	77	05104620001105	AA97220-01 05104620001105 14 N/A Serum-1 1 / Day 1 - 0333h
14	N/A	2 / Day 1 0h	6872 66	139391 492	*0 049305	5	*BLQ<(2 50)	82	05104620001074	AA97220-01 05104620001074 14 N/A Serum-1 2 / Day 1 0h
14	N/A	2 / Day 1 0h	8100 808	147509 527	*0 054917	5	*BLQ<(2 50)	80	05104620001090	AA97220-01 05104620001090 14 N/A Serum-1 2 / Day 1 0h
14	N/A	2 / Day 1 0h	6615 395	133718 248	*0 049473	5	*BLQ<(2 50)	81	05104620001106	AA97220-01 05104620001106 14 N/A Serum-1 2 / Day 1 0h
14	N/A	3 / Day 1 0 05h	6803 75	144424 841	*0 047109	5	*BLQ<(2 50)	86	05104620001075	AA97220-01 05104620001075 14 N/A Serum-1 3 / Day 1 0 05h
14	N/A	3 / Day 1 0 05h	7045 815	151543 407	*0 046494	5	*BLQ<(2 50)	84	05104620001091	AA97220-01 05104620001091 14 N/A Serum-1 3 / Day 1 0 05h
14	N/A	3 / Day 1 0 05h	30465 41	156315 262	*0 194897	5	*3 69	85	05104620001107	AA97220-01 05104620001107 14 N/A Serum-1 3 / Day 1 0 05h
14	N/A	4 / Day 1 0 0833h	13475 46	159385 912	*0 084546	5	*BLQ<(2 50)	88	05104620001076	AA97220-01 05104620001076 14 N/A Serum-1 4 / Day 1 0 0833h
14	N/A	4 / Day 1 0 0833h	10647 945	157130 173	*0 067765	5	*BLQ<(2 50)	89	05104620001092	AA97220-01 05104620001092 14 N/A Serum-1 4 / Day 1 0 0833h
14	N/A	4 / Day 1 0 0833h	43533 572	144208 368	*0 301880	5	*5 84	87	05104620001108	AA97220-01 05104620001108 14 N/A Serum-1 4 / Day 1 0 0833h
14	N/A	5 / Day 1 0 125h	12654 71	144583 97	*0 087525	5	*BLQ<(2 50)	90	05104620001093	AA97220-01 05104620001093 14 N/A Serum-1 5 / Day 1 125h

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)

AAR - Concentration Found is Greater than 50 0 (Highest Standard)

* - Sample Rejected

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 38
 Serum, Concentration of Nicotine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		0	213734 026	0 000000	-0 0225		-0 0225	0 0
9	0 00		0	259495 931	0 000000	-0 0225			
10	0 500	4 00000	24450 718	191321 174	0 127799	0 498	-0 4		
11	1 00	1 00000	49316 31	194021 028	0 254180	1 01	1 0		
12	2 00	0 250000	105341 828	220426 178	0 477901	1 92	-4 0		
13	4 00	0 0625000	228666 962	218900 708	1 044615	4 23	5 8		
14	8 00	0 0156250	413545 086	214235 211	1 930332	7 84	-2 0		
15	10 0	0 0100000	546362 988	220682 778	2 475784	10 1	1 0		
16	20 0	0 00250000	1048141 299	203654 054	5 146675	20 9	4 5		
17	40 0	0 000625000	2166966 022	225812 146	9 596322	39 1	-2 3		
18	50 0	0 000400000	2431169 839	206165 574	11 792317	48 0	-4 0		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:
 Slope = 0 245482578
 Intercept = 0 00552754113
 R-Squared = 0 9983

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)
 AAR - Concentration Found is Greater than 50 0 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 38
 Serum, Concentration of Nicotine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	2666099 71	208673 385	12 776424	1	52 0		50 4		2 4
2	0 00	2505945 177	204822 311	12 234728	1	49 8				
3	0 00	2415027 128	200345 715	12 054299	1	49 1				
4	0 00	2913168 78	235550 939	12 367468	1	50 4				
5	0 00	2332878 728	193142 711	12 078523	1	49 2				
92	0 00	2624464 333	205512 811	12 770320	1	52 0				
93	0 00	2647577 301	214178 213	12 361562	1	50 3				
34	1 50	70547 167	195730 122	0 360431	1	1 45	-3 3	1 44	-4 0	1 0
63	1 50	67041 397	188211 852	0 356202	1	1 43	-4 7			
41	8 00	401325 777	226760 287	1 769824	1	7 19	-10 1	7 12	-11 0	1 4
70	8 00	374081 592	215442 592	1 736340	1	7 05	-11 9			
26	37 5	461367 672	188893 5	2 442475	4	39 7	5 9	38 1	1 6	6 6
55	37 5	559616 117	230619 446	2 426578	4	39 4	5 1			
77	37 5	575493 614	265725 814	2 165742	4	35 2	-6 1			
27	37 5	1006206 267	218714 239	4 600552	2	37 4	-0 3	38 3	2 1	2 8
56	37 5	960919 832	198114 152	4 850334	2	39 5	5 3			
78	37 5	1050333 724	224048 364	4 687978	2	38 1	1 6			
48	37 5	1875728 116	196250 116	9 557845	1	38 9	3 7	37 5	0 0	5 3
90	37 5	2131682 959	240680 424	8 856902	1	36 1	-3 7			

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)
 AAR - Concentration Found is Greater than 50 0 (Highest Standard)

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 38
Serum, Concentration of Nicotine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
01	N/A	5 / Day 1 0 125h	1004648 746	207821 783	4 834184	1	19 7	20	05104620000069	AA97220-01 05104620000069 01 N/A Serum-1 5 / Day 1 125h
01	N/A	8 / Day 1 0 333h	70772 098	217197 044	0 325843	1	1 30	21	05104620000056	AA97220-01 05104620000056 01 N/A Serum-1 8 / Day 1 333h
01	N/A	9 / Day 1 0 5h	196602 95	210024 184	0 936097	1	3 79	24	05104620000009	AA97220-01 05104620000009 01 N/A Serum-1 9 / Day 1 5h
01	N/A	16 / Day 1 3h	90518 191	206072 755	0 439254	1	1 77	25	05104620000016	AA97220-01 05104620000016 01 N/A Serum-1 16 / Day 1 3h
01	N/A	16 / Day 1 3h	48643 078	196642 507	0 247368	1	0 985	23	05104620000032	AA97220-01 05104620000032 01 N/A Serum-1 16 / Day 1 3h
01	N/A	16 / Day 1 3h	51863 133	247549 51	0 209506	1	0 831	22	05104620000048	AA97220-01 05104620000048 01 N/A Serum-1 16 / Day 1 3h
02	N/A	8 / Day 1 0 333h	87435 187	246173 293	0 355177	1	1 42	32	05104620000088	AA97220-01 05104620000088 02 N/A Serum-1 8 / Day 1 333h
02	N/A	16 / Day 1 3h	48859 742	207592 588	0 235364	1	0 936	33	05104620000096	AA97220-01 05104620000096 02 N/A Serum-1 16 / Day 1 3h
02	N/A	16 / Day 1 3h	136041 533	230015 38	0 591445	1	2 39	31	05104620000112	AA97220-01 05104620000112 02 N/A Serum-1 16 / Day 1 3h
02	N/A	16 / Day 1 3h	48511 206	206994 243	0 234360	1	0 932	30	05104620000128	AA97220-01 05104620000128 02 N/A Serum-1 16 / Day 1 3h
02	N/A	16 / Day 1 3h	35585 708	201879 829	0 176272	1	0 696	29	05104620000144	AA97220-01 05104620000144 02 N/A Serum-1 16 / Day 1 3h
02	N/A	16 / Day 1 3h	82136 574	187111 079	0 438972	1	1 77	28	05104620000160	AA97220-01 05104620000160 02 N/A Serum-1 16 / Day 1 3h
03	N/A	5 / Day 1 0 125h	88954 818	234995 172	0 378539	2	3 04	38	05104620000181	AA97220-01 05104620000181 03 N/A Serum-1 5 / Day 1 125h
03	N/A	7 / Day 1 0 25h	433576 729	212418 568	2 041143	2	16 6	35	05104620000231	AA97220-01 05104620000231 03 N/A Serum-1 7 / Day 1 25h
03	N/A	16 / Day 1 3h	88894 711	209785 394	0 423741	2	3 41	39	05104620000192	AA97220-01 05104620000192 03 N/A Serum-1 16 / Day 1 3h
03	N/A	16 / Day 1 3h	101813 54	202216 263	0 503488	2	4 06	37	05104620000208	AA97220-01 05104620000208 03 N/A Serum-1 16 / Day 1 3h
03	N/A	16 / Day 1 3h	173439 076	199502 404	0 869358	2	7 04	36	05104620000240	AA97220-01 05104620000240 03 N/A Serum-1 16 / Day 1 3h
04	N/A	4 / Day 1 0 0833h	2492975 21	241957 597	10 303356	1	41 9	40	05104620000308	AA97220-01 05104620000308 04 N/A Serum-1 4 / Day 1 0833h
04	N/A	6 / Day 1 0 1667h	197009 273	230041 347	0 856408	1	3 47	46	05104620000246	AA97220-01 05104620000246 04 N/A Serum-1 6 / Day 1 1667h
04	N/A	8 / Day 1 0 333h	255715 351	254642 144	1 004215	1	4 07	44	05104620000264	AA97220-01 05104620000264 04 N/A Serum-1 8 / Day 1 333h
04	N/A	9 / Day 1 0 5h	197033 085	242179 542	0 813583	2	6 58	42	05104620000297	AA97220-01 05104620000297 04 N/A Serum-1 9 / Day 1 5h
04	N/A	16 / Day 1 3h	32552 985	202471 78	0 160778	1	0 632	47	05104620000256	AA97220-01 05104620000256 04 N/A Serum-1 16 / Day 1 3h
04	N/A	16 / Day 1 3h	45998 594	209375 028	0 219695	1	0 872	45	05104620000272	AA97220-01 05104620000272 04 N/A Serum-1 16 / Day 1 3h
04	N/A	16 / Day 1 3h	53427 249	221394 527	0 241321	2	1 92	43	05104620000304	AA97220-01 05104620000304 04 N/A Serum-1 16 / Day 1 3h
05	N/A	6 / Day 1 0 1667h	108961 23	241072 568	0 451985	2	3 64	49	05104620000374	AA97220-01 05104620000374 05 N/A Serum-1 6 / Day 1 1667h
05	N/A	9 / Day 1 0 5h	71066 238	239742 874	0 296427	2	2 37	51	05104620000361	AA97220-01 05104620000361 05 N/A Serum-1 9 / Day 1 5h
05	N/A	10 / Day 1 0 75h	85546 98	217740 965	0 392884	2	3 16	53	05104620000330	AA97220-01 05104620000330 05 N/A Serum-1 10 / Day 1 75h
05	N/A	16 / Day 1 3h	110866 021	244494 448	0 453450	1	1 82	54	05104620000336	AA97220-01 05104620000336 05 N/A Serum-1 16 / Day 1 3h
05	N/A	16 / Day 1 3h	80271 011	254548 603	0 315346	1	1 26	52	05104620000368	AA97220-01 05104620000368 05 N/A Serum-1 16 / Day 1 3h
05	N/A	16 / Day 1 3h	44954 145	195031 523	0 230497	2	1 83	50	05104620000384	AA97220-01 05104620000384 05 N/A Serum-1 16 / Day 1 3h
06	N/A	10 / Day 1 0 75h	84635 504	243883 933	0 347032	1	1 39	58	05104620000410	AA97220-01 05104620000410 06 N/A Serum-1 10 / Day 1 75h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
06	N/A	15 / Day 1 2 5h	39157 921	197662 122	0 198105	1	0 784	59	05104620000415	AA97220-01 05104620000415 06 N/A Serum-1 15 / Day 1 2 5h
06	N/A	16 / Day 1 3h	39536 695	192465 802	0 205422	1	0 814	57	05104620000464	AA97220-01 05104620000464 06 N/A Serum-1 16 / Day 1 3h
07	N/A	6 / Day 1 0 1667h	515227 438	217653 19	2 367195	1	9 62	60	05104620000550	AA97220-01 05104620000550 07 N/A Serum-1 6 / Day 1 1667h
07	N/A	16 / Day 1 3h	125655 768	214905 751	0 584702	1	2 36	61	05104620000560	AA97220-01 05104620000560 07 N/A Serum-1 16 / Day 1 3h
10	N/A	9 / Day 1 0 5h	117730 181	200372 888	0 587555	2	4 74	64	05104620000729	AA97220-01 05104620000729 10 N/A Serum-1 9 / Day 1 5h
10	N/A	10 / Day 1 0 75h	129722 768	231968 015	0 559227	2	4 51	62	05104620000746	AA97220-01 05104620000746 10 N/A Serum-1 10 / Day 1 75h
10	N/A	16 / Day 1 3h	42230 612	183312 052	0 230376	2	1 83	65	05104620000736	AA97220-01 05104620000736 10 N/A Serum-1 16 / Day 1 3h
11	N/A	8 / Day 1 0 333h	60642 093	242498 393	0 250072	2	1 99	68	05104620000840	AA97220-01 05104620000840 11 N/A Serum-1 8 / Day 1 333h
11	N/A	13 / Day 1 1 5h	57097 507	253709 451	0 225051	2	1 79	67	05104620000861	AA97220-01 05104620000861 11 N/A Serum-1 13 / Day 1 1 5h
11	N/A	16 / Day 1 3h	27004 264	218327 939	*0 123687	2	*BLQ<(1 00)	69	05104620000848	AA97220-01 05104620000848 11 N/A Serum-1 16 / Day 1 3h
11	N/A	16 / Day 1 3h	63575 858	198715 92	0 319933	2	2 56	66	05104620000880	AA97220-01 05104620000880 11 N/A Serum-1 16 / Day 1 3h
12	N/A	4 / Day 1 0 0833h	643796 834	262275 952	2 454654	4	39 9	71	05104620000948	AA97220-01 05104620000948 12 N/A Serum-1 4 / Day 1 0833h
12	N/A	8 / Day 1 0 333h	69869 993	205859 238	0 339407	4	5 44	72	05104620000936	AA97220-01 05104620000936 12 N/A Serum-1 8 / Day 1 333h
12	N/A	10 / Day 1 0 75h	259970 656	219810 979	1 182701	4	19 2	76	05104620000890	AA97220-01 05104620000890 12 N/A Serum-1 10 / Day 1 75h
12	N/A	16 / Day 1 3h	137814 176	230201 45	0 598668	4	9 66	79	05104620000896	AA97220-01 05104620000896 12 N/A Serum-1 16 / Day 1 3h
12	N/A	16 / Day 1 3h	70218 05	212289 051	0 330766	4	5 30	75	05104620000912	AA97220-01 05104620000912 12 N/A Serum-1 16 / Day 1 3h
12	N/A	16 / Day 1 3h	70797 532	251472 415	0 281532	4	4 50	74	05104620000928	AA97220-01 05104620000928 12 N/A Serum-1 16 / Day 1 3h
12	N/A	16 / Day 1 3h	38311 415	233065 239	0 164381	4	2 59	73	05104620000944	AA97220-01 05104620000944 12 N/A Serum-1 16 / Day 1 3h
13	N/A	7 / Day 1 0 25h	109922 357	246712 232	0 445549	1	1 79	82	05104620000983	AA97220-01 05104620000983 13 N/A Serum-1 7 / Day 1 25h
13	N/A	9 / Day 1 0 5h	208780 493	206882 04	1 009176	1	4 09	81	05104620001001	AA97220-01 05104620001001 13 N/A Serum-1 9 / Day 1 5h
13	N/A	10 / Day 1 0 75h	105583 235	201305 806	0 524492	1	2 11	84	05104620000970	AA97220-01 05104620000970 13 N/A Serum-1 10 / Day 1 75h
13	N/A	10 / Day 1 0 75h	67428 523	226880 511	0 297198	2	2 38	80	05104620001018	AA97220-01 05104620001018 13 N/A Serum-1 10 / Day 1 75h
13	N/A	16 / Day 1 3h	55930 14	257126 961	0 217520	1	0 864	83	05104620000992	AA97220-01 05104620000992 13 N/A Serum-1 16 / Day 1 3h
14	N/A	8 / Day 1 0 333h	269696 516	215319 562	1 252541	2	10 2	85	05104620001112	AA97220-01 05104620001112 14 N/A Serum-1 8 / Day 1 333h
14	N/A	9 / Day 1 0 5h	87523 459	204220 318	0 428574	2	3 45	87	05104620001081	AA97220-01 05104620001081 14 N/A Serum-1 9 / Day 1 5h
14	N/A	16 / Day 1 3h	37712 486	190357 694	0 198114	2	1 57	88	05104620001072	AA97220-01 05104620001072 14 N/A Serum-1 16 / Day 1 3h
14	N/A	16 / Day 1 3h	108635 577	200389 503	0 542122	2	4 37	86	05104620001120	AA97220-01 05104620001120 14 N/A Serum-1 16 / Day 1 3h
15	N/A	16 / Day 1 3h	107800 414	183429 317	0 587695	2	4 74	89	05104620001200	AA97220-01 05104620001200 15 N/A Serum-1 16 / Day 1 3h

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)
AAR - Concentration Found is Greater than 50 0 (Highest Standard)

* - Sample Rejected

Standard Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 39
 Serum, Concentration of Nicotine (ng/mL)

Sample No	Nom Conc	Wgt	Area	IntStd Area	Response Value	Conc Found	%Bias	Mean Conc	%CV
8	0 00		2260 804	241027 691	0 009380	0 0172		0 0163	7 8
9	0 00		1822 852	203873 139	0 008941	0 0154			
10	0 500	4 00000	32441 295	242094 477	0 134003	0 506	1 2		
11	1 00	1 00000	65234 606	254351 514	0 256474	0 987	-1 3		
12	2 00	0 250000	100777 771	203587 036	0 495011	1 92	-4 0		
13	4 00	0 0625000	250047 794	237346 671	1 053513	4 12	3 0		
14	8 00	0 0156250	420754 106	213221 854	1 973316	7 73	-3 4		
15	10 0	0 0100000	592336 656	226597 339	2 614049	10 2	2 0		
16	20 0	0 00250000	952140 935	186105 989	5 116122	20 1	0 5		
17	40 0	0 000625000	2478570 207	240251 058	10 316584	40 5	1 3		
18	50 0	0 000400000	2222480 23	173927 22	12 778220	50 1	0 2		

Model: Response = Slope * Concentration + Intercept

Curve Parameters:
 Slope = 0 254702648
 Intercept = 0 00501091336
 R-Squared = 0 9992

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)
 AAR - Concentration Found is Greater than 50 0 (Highest Standard)

QC Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 39
 Serum, Concentration of Nicotine (ng/mL)

Sample No	Nom Conc	Area	IntStd Area	Response Value	Dilution Factor	Conc Found	%Bias	Mean Conc	Mean %Bias	%CV
1	0 00	2592151 132	204937 413	12 648501	1	49 6		50 0		2 4
2	0 00	2980562 335	229431 489	12 991078	1	51 0				
3	0 00	2937005 526	222491 666	13 200519	1	51 8				
4	0 00	2869546 605	231676 666	12 385997	1	48 6				
5	0 00	2489193 375	195846 429	12 709925	1	49 9				
71	0 00	2319615 299	187336 827	12 382057	1	48 6				
72	0 00	2394146 948	184924 48	12 946620	1	50 8				
30	1 50	66913 911	176520 043	0 379073	1	1 47	-2 0	1 44	-4 0	3 4
51	1 50	72818 7	201704 339	0 361017	1	1 40	-6 7			
35	8 00	375866 683	205705 228	1 827210	1	7 15	-10 6	6 94	-13 3	4 4
56	8 00	340410 104	198450 017	1 715344	1	6 72	-16 0			
24	37 5	371415 377	193499 094	1 919468	5	37 6	0 3	36 6	-2 4	2 6
45	37 5	325137 092	178147 209	1 825103	5	35 7	-4 8			
61	37 5	332068 63	177530 1	1 870492	5	36 6	-2 4			
25	37 5	1008347 08	207421 019	4 861354	2	38 1	1 6	37 3	-0 5	3 6
46	37 5	866089 086	190273 321	4 551816	2	35 7	-4 8			
62	37 5	770136 834	159032 533	4 842637	2	38 0	1 3			
40	37 5	1680970 084	182358 185	9 217958	1	36 2	-3 5	35 2	-6 1	4 2
69	37 5	1722411 834	197964 447	8 700612	1	34 1	-9 1			

Response Type = Area Ratio

BLQ - Concentration Found is Less than 0 500 (Lowest Standard)
 AAR - Concentration Found is Greater than 50 0 (Highest Standard)

Study Sample Data

R J Reynolds Tobacco Company Study: AA97220-01 RJR Nicotine Batch 39
Serum, Concentration of Nicotine (ng/mL)

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
13	N/A	1 / Day 1 -0 0333h	11132 8	200977 817	*0 055393	5	*BLQ<(2 50)	63	05104620001009	AA97220-01 05104620001009 13 N/A Serum-1 1 / Day 1 - 0333h
13	N/A	2 / Day 1 0h	7955 13	166682 735	*0 047726	5	*BLQ<(2 50)	64	05104620001010	AA97220-01 05104620001010 13 N/A Serum-1 2 / Day 1 0h
13	N/A	3 / Day 1 0 05h	9273 821	174920 364	*0 053017	5	*BLQ<(2 50)	65	05104620001011	AA97220-01 05104620001011 13 N/A Serum-1 3 / Day 1 05h
13	N/A	4 / Day 1 0 0833h	10693 733	190746 24	*0 056063	5	*BLQ<(2 50)	66	05104620001012	AA97220-01 05104620001012 13 N/A Serum-1 4 / Day 1 0833h
13	N/A	6 / Day 1 0 1667h	15758 137	222874 654	*0 070704	5	*BLQ<(2 50)	68	05104620001014	AA97220-01 05104620001014 13 N/A Serum-1 6 / Day 1 1667h
13	N/A	6 / Day 1 0 1667h	0	0	*N/A	1	*BLQ<(0 500)	67	05104620001030	AA97220-01 05104620001030 13 N/A Serum-1 6 / Day 1 1667h
14	N/A	16 / Day 1 3h	66756 883	207537 068	0 321662	1	1 24	39	05104620001088	AA97220-01 05104620001088 14 N/A Serum-1 16 / Day 1 3h
15	N/A	10 / Day 1 0 75h	94155 515	209529 206	*0 449367	2	*3 49	23	05104620001146	AA97220-01 05104620001146 15 N/A Serum-1 10 / Day 1 75h
15	N/A	10 / Day 1 0 75h	77589 605	180991 664	*0 428692	2	*3 33	22	05104620001162	AA97220-01 05104620001162 15 N/A Serum-1 10 / Day 1 75h
15	N/A	10 / Day 1 0 75h	164645 067	170468 997	*0 965836	2	*7 54	20	05104620001178	AA97220-01 05104620001178 15 N/A Serum-1 10 / Day 1 75h
15	N/A	16 / Day 1 3h	84853 041	181850 23	*0 466609	2	*3 62	27	05104620001136	AA97220-01 05104620001136 15 N/A Serum-1 16 / Day 1 3h
15	N/A	16 / Day 1 3h	122549 042	185339 91	*0 661212	1	*2 58	26	05104620001152	AA97220-01 05104620001152 15 N/A Serum-1 16 / Day 1 3h
15	N/A	16 / Day 1 3h	114998 153	204709 545	*0 561763	2	*4 37	21	05104620001184	AA97220-01 05104620001184 15 N/A Serum-1 16 / Day 1 3h
16	N/A	4 / Day 1 0 0833h	570528 549	191907 441	*2 972936	2	*23 3	28	05104620001268	AA97220-01 05104620001268 16 N/A Serum-1 4 / Day 1 0833h
16	N/A	8 / Day 1 0 333h	100315 133	183927 154	*0 545407	2	*4 24	29	05104620001256	AA97220-01 05104620001256 16 N/A Serum-1 8 / Day 1 333h
16	N/A	9 / Day 1 0 5h	99504 02	205486 081	*0 484237	2	*3 76	32	05104620001225	AA97220-01 05104620001225 16 N/A Serum-1 9 / Day 1 5h
16	N/A	16 / Day 1 3h	58577 122	210796 819	*0 277884	2	*2 14	33	05104620001232	AA97220-01 05104620001232 16 N/A Serum-1 16 / Day 1 3h
16	N/A	16 / Day 1 3h	77041 441	167802 182	*0 459121	1	*1 78	31	05104620001248	AA97220-01 05104620001248 16 N/A Serum-1 16 / Day 1 3h
17	N/A	1 / Day 1 -0 0333h	14561 522	219684 41	*0 066284	5	*BLQ<(2 50)	41	05104620001281	AA97220-01 05104620001281 17 N/A Serum-1 1 / Day 1 - 0333h
17	N/A	2 / Day 1 0h	10039 832	178388 506	*0 056281	5	*BLQ<(2 50)	42	05104620001282	AA97220-01 05104620001282 17 N/A Serum-1 2 / Day 1 0h
17	N/A	3 / Day 1 0 05h	7298 448	173068 658	*0 042171	5	*BLQ<(2 50)	43	05104620001283	AA97220-01 05104620001283 17 N/A Serum-1 3 / Day 1 05h
17	N/A	4 / Day 1 0 0833h	10546 937	204486 256	*0 051578	5	*BLQ<(2 50)	44	05104620001284	AA97220-01 05104620001284 17 N/A Serum-1 4 / Day 1 0833h
17	N/A	5 / Day 1 0 125h	9712 442	165827 467	*0 058570	5	*BLQ<(2 50)	47	05104620001285	AA97220-01 05104620001285 17 N/A Serum-1 5 / Day 1 125h
17	N/A	6 / Day 1 0 1667h	12147 948	172677 03	*0 070351	5	*BLQ<(2 50)	48	05104620001286	AA97220-01 05104620001286 17 N/A Serum-1 6 / Day 1 1667h
17	N/A	7 / Day 1 0 25h	16873 277	203426 481	*0 082945	5	*BLQ<(2 50)	49	05104620001287	AA97220-01 05104620001287 17 N/A Serum-1 7 / Day 1 25h
17	N/A	8 / Day 1 0 333h	23972 144	157666 945	*0 152043	5	*2 89	50	05104620001288	AA97220-01 05104620001288 17 N/A Serum-1 8 / Day 1 333h
17	N/A	9 / Day 1 0 5h	41741 178	188667 742	*0 221242	5	*4 24	52	05104620001289	AA97220-01 05104620001289 17 N/A Serum-1 9 / Day 1 5h
17	N/A	9 / Day 1 0 5h	89644 389	192187 195	*0 466443	2	*3 62	37	05104620001305	AA97220-01 05104620001305 17 N/A Serum-1 9 / Day 1 5h
17	N/A	10 / Day 1 0 75h	37336 604	203910 82	*0 183103	5	*3 50	53	05104620001290	AA97220-01 05104620001290 17 N/A Serum-1 10 / Day 1 75h
17	N/A	11 / Day 1 1h	28761 097	190605 887	*0 150893	5	*2 86	54	05104620001291	AA97220-01 05104620001291 17 N/A Serum-1 11 / Day 1 1h
17	N/A	12 / Day 1 1 25h	25417 065	185012 876	*0 137380	5	*2 60	55	05104620001292	AA97220-01 05104620001292 17 N/A Serum-1 12 / Day 1 1 25h

Subject No	Trt Code	Time (Standard)	Area	IntStd Area	Response Value	Dilution Factor	Conc	Sample No	Barcode	Sample Name
17	N/A	13 / Day 1 1 5h	24470 881	222772 486	*0 109847	5	*BLQ<(2 50)	57	05104620001293	AA97220-01 05104620001293 17 N/A Serum-1 13 / Day 1 1 5h
17	N/A	14 / Day 1 2h	17373 685	173706 4	*0 100018	5	*BLQ<(2 50)	58	05104620001294	AA97220-01 05104620001294 17 N/A Serum-1 14 / Day 1 2h
17	N/A	15 / Day 1 2 5h	15729 465	185478 2	*0 084805	5	*BLQ<(2 50)	59	05104620001295	AA97220-01 05104620001295 17 N/A Serum-1 15 / Day 1 2 5h
17	N/A	16 / Day 1 3h	15696 172	171007 01	*0 091787	5	*BLQ<(2 50)	60	05104620001296	AA97220-01 05104620001296 17 N/A Serum-1 16 / Day 1 3h
17	N/A	16 / Day 1 3h	37221 676	202750 221	*0 183584	2	*1 40	38	05104620001312	AA97220-01 05104620001312 17 N/A Serum-1 16 / Day 1 3h
17	N/A	16 / Day 1 3h	27662 42	161104 604	*0 171705	2	*1 31	36	05104620001328	AA97220-01 05104620001328 17 N/A Serum-1 16 / Day 1 3h
17	N/A	16 / Day 1 3h	74520 942	214505 738	*0 347408	2	*2 69	34	05104620001360	AA97220-01 05104620001360 17 N/A Serum-1 16 / Day 1 3h

Response Type = Area Ratio

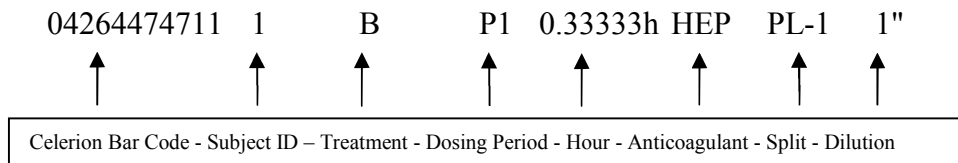
BLQ - Concentration Found is Less than 0 500 (Lowest Standard)
AAR - Concentration Found is Greater than 50 0 (Highest Standard)

* - Sample Rejected

Attachment 6. Chromatograms

Chromatograms from Batches 1 - 5

Each chromatogram has a sample file name at the top left hand side. The first number in the name represent the batch number, the next number in the name represents the injection number within the batch. Following the injection number is the Celerion study number. Following the Celerion Study number is the unique sample identification as indicated below.



Results from the initial baseline integration and any subsequent re-integration are on file at Celerion, Lincoln, Nebraska.

