

# CRF Report for Study E8230249

Report run by Tamara Fisher at 13-AUG-2014 17:47:04

## Report Parameters

Site: M01

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: 1053

Ending patient: 1053

## Legend: How different values appear in the report

Prompt	Abc 123
Data value	Abc 123
Data value with discrepancy	<b>Abc</b> 123

All time stamps displayed in this report are in the timezone of the database server.

The data contained in this report is current at the time of printing (time as shown above)



R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

1053

Subject Initials:

(b) (6)

Is Blank

Investigator:

MANDARINO

Information Correct?

☒ Yes ☐ No

# REMOTE DATA CAPTURE CASE REPORT FORM

SWITCHING FROM USUAL BRAND CIGARETTES TO CAMEL "SNUS," CAMEL  
DISSOLVABLE TOBACCO "STICKS," "STRIPS," OR "ORBS," DUAL USE OF USUAL  
BRAND CIGARETTES AND SNUS, OR TOBACCO ABSTINENCE -  
A MULTI-CENTER EVALUATION OF SELECT MODERN SMOKE-FREE TOBACCO PRODUCTS

Protocol No. CSD0901

Covance Study No. 8230249

for

R.J. Reynolds Tobacco Company  
Bowman Gray Technical Center  
950 Reynolds Boulevard  
Winston-Salem, North Carolina 27105

by

Covance Clinical Pharmacology Inc.  
3402 Kinsman Boulevard  
Madison, Wisconsin 53704

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Page Version No. PAGE\_01 (v1, 18-OCT-2010)

Document Number R340142513

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

1053

Subject Initials:

(b) (6)

Is Blank

### Inclusion Criteria

Subjects who meet the following criteria may be included in the study. Did the subject meet the following criteria requirements for inclusion? (Check Yes or No)

		Yes	No*
01	Between 21 and 65 years of age, inclusive.	YES	
02	Self-reported daily use $\geq$ 10 cigarettes/day for $\geq$ 12 months.	YES	
03	Screening Fagerström dependence score of "low" or greater (ie, 3 to 10).	YES	
04	Screening urinary cotinine $\geq$ 200 ng/mL (via NicCheck I Test Strips with a positive result).	YES	
05	Screening expired-air CO level $\geq$ 15 ppm (sample taken 30-60 minutes after smoking a single UB cigarette).	YES	
06	No intent to quit smoking during the trial period.	YES	
07	Willing to either switch cigarette use to any one of the MSFT test products, or completely abstain from smoking or using any tobacco products, for a period of 5 consecutive days + the next morning.	YES	
08	After confinement, able to adhere to a controlled diet for the duration of the trial, that prohibits drinking "full-bodied" beer and eating grilled, charbroiled, smoked or smoke-flavored foods, almond nuts, and kale.	YES	
09	In the opinion of the Investigators, participants will be free of clinically significant health problems.	YES	
10	Negative tests for selected drugs of abuse at Screening and on Day -2.	YES	
11	Negative hepatitis panel (including HBsAg and anti-HCV) and negative HIV antibody screens (for participants who self-report they have been immunized against hepatitis B, a positive test result is not exclusionary).	YES	

\*If No, document on Subject Eligibility Page.

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Page Version No. PAGE\_02 (v1, 18-OCT-2010)

Document Number R340142613

## **Links to Discrepancy and Audit Sections**

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R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

1053

Subject Initials:

(b) (6)

Is Blank

☐

### Inclusion Criteria

Subjects who meet the following criteria may be included in the study. Did the subject meet the following criteria requirements for inclusion? (Check Yes or No)

Yes No\*

1.2

Females will be non-pregnant (for all females, the urine pregnancy test results must be negative at Screening; and for all females of child-bearing potential, the pregnancy test results must be negative at Day -2), non lactating, and either postmenopausal (as verified by follicle stimulating hormone [FSH] levels) for at least 1 year, surgically sterile (tubal ligation, hysterectomy, etc.) for at least 90 days, or agree to use from the time of signing the informed consent until 30 days after Day 6 (or Trial Completion) a form of contraception considered acceptable to the Investigators: a non-hormonal IUD with spermicide; female condom with spermicide; contraceptive sponge with spermicide; diaphragm with spermicide; cervical cap with spermicide; an intravaginal system (eg, NuvaRing); oral, implantable, transdermal, or injectable contraceptives; a male sexual partner who agrees to use a male condom with spermicide; or a sterile sexual partner.

NAM

1.3

Able to read, understand and complete informed consent documents and questionnaires in English.

YES

\*If No, document on Subject Eligibility Page.

Verified



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Document Number

R340142713

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

1053

Subject Initials:

(b) (6)

Is Blank

☐

#### Exclusion Criteria

The following will exclude potential subjects from the study. Does the subject have any of the following?  
(Check Yes or No)

	Yes*	No
01 Use of any type of smokeless tobacco or non-tobacco nicotine-containing product(s), or smoked marijuana-based materials within 30 days prior to trial start.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
02 Have any unacceptable 'safety' clinical evaluations.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
03 Use of injectable forms of medication (except birth control).	<input type="checkbox"/>	<input checked="" type="checkbox"/>
04 Any self-reported or clinical indication(s) of acute or chronic health or psychiatric disorders that, in the Investigator(s)' opinion, would place participants in an unacceptable risk, or limit the participants ability to participate in and/or complete this clinical trial.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
05 Intent to become pregnant during trial period, or current pregnancy or breast feeding.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
06 History of hypersensitivity or allergies to any drug compound unless approved by the Investigator(s).	<input type="checkbox"/>	<input checked="" type="checkbox"/>
07 Poor peripheral venous access.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
08 Donation of blood from 30 days prior to Screening through Day 6 (or Trial Completion), inclusive; or of plasma from 2 weeks prior to Screening through Day 6 (or Trial Completion), inclusive.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
09 Participant is an employee of Covance or RJRT.	<input type="checkbox"/>	<input checked="" type="checkbox"/>

\*If Yes, document on Subject Eligibility Page.

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Document Number R340142913

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

### Subject Eligibility

Date the Subject Signed the Informed Consent Form:   
DD/MMM/YYYY

---

Did the subject meet all of the inclusion/exclusion criteria? ☒ Yes ☐ No

If the subject did not meet all of the Inclusion/Exclusion criteria, provide criterion number and explanation below.

Category	Inclusion/ Exclusion No.	Explanation	Exemption Granted?	If Yes, Date Granted DD/MMM/YYYY
<input type="checkbox"/> Inclusion <input type="checkbox"/> Exclusion	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="checkbox"/> Inclusion <input type="checkbox"/> Exclusion	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="checkbox"/> Inclusion <input type="checkbox"/> Exclusion	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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Document Number



R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

1053

Subject Initials:

(b) (6)

Is Blank

#### Tobacco Abstinence Question

Was Tobacco Abstinence Question asked? ☒ Yes ☐ No

Date

DD/MMM/YYYY

22-OCT-2010

Willing to be tobacco abstinent for a 5-day period?

☒ Yes ☐ No

#### Fagerström (FTND) Questionnaire

Was FTND Questionnaire administered? ☒ Yes ☐ No

Date

DD/MMM/YYYY

22-OCT-2010

Score

3

Comments

#### Urine Cotinine Screen

Date

DD/MMM/YYYY

22-OCT-2010

Actual Time  
24-hour clock

09:44

NicCheck I  
Results

☒ Positive  
☐ Negative

Not Done

☐

Comments

Verified

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Document Number

R340143213

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

1053

Subject Initials:

(b) (6)

Is Blank

#### MSFT Taste Test

Was MSFT Taste Test administered? ☒ Yes ☐ No

Date

DD/MMM/YYYY

22-OCT-2010

Product

Is taste of product acceptable? (Note: only one 'Yes' for SNUS is required)

SNUS Frost

☒ Yes ☐ No

SNUS Mellow

☒ Yes ☐ No

Preferred SNUS Type

☐ Frost ☒ Mellow ☐ None

Sticks

☒ Yes ☐ No

Strips

☒ Yes ☐ No

Orbs

☒ Yes ☐ No

#### Demographics

Date

DD/MMM/YYYY

22-OCT-2010

Date of Birth

DD/MMM/YYYY

(b) (6)

Gender

☒ Male

☐ Female

Ethnicity

☐ Hispanic or Latino

☒ Not Hispanic or Latino

Race

☒ White

☐ Black or African American

☐ Asian

☐ Native Hawaiian or Other Pacific Islander

☐ American Indian/Alaskan Native

☐ Other:

Verified

☒ Approved

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☒ Frozen

☒

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Document Number

R340143513

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

1053

Subject Initials:

(b) (6)

Is Blank

### Seated Vital Signs and HDYF? Inquiry

Were vital signs collected? ☒ Yes ☐ No

Date  
DD/MMM/YYYY

22-OCT-2010

Actual Time  
24-hour clock

09:01

Was HDYF?  
question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

139

Diastolic Blood Pressure

mmHg

85

Pulse

beats/minute

68

Respiratory Rate

breaths/minute

18

Oral Temperature

°C

36.1

### Body Measurements

Were Body Measurements Collected? ☒ Yes ☐ No

Date

DD/MMM/YYYY

22-OCT-2010

Parameter

Unit

Result

Height

cm

178.8

Weight

kg

100.8

BMI

kg/m<sup>2</sup>

31.5

Note: Body Mass Index will be derived.

Verified



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Page Version No. PAGE\_08 (v1, 15-OCT-2010)

Document Number

R340143713

## **Links to Discrepancy and Audit Sections**

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R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

1053

Subject Initials:

(b) (6)

Is Blank

#### Laboratory Evaluations

Were the scheduled laboratory samples obtained?

☒ Yes ☐ No (Specify samples not done, reason):

Date

DD/MMM/YYYY

22-OCT-2010

Evaluations: Chem-19 and HgbA1c (fasted at least 8 hours), CBC, and Urinalysis; FSH & Estradiol (women only); Hepatitis Panel & HIV Screen

Requisition Number 1:

Y546156

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

Requisition Number 4 (if applicable):

Requisition Number 5 (if applicable):

Were there any clinically significant labs? ☐ Yes (specify below) ☒ No

Requisition Number

Test Name

Test Code ID


Verified



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Document Number

R341494813

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number: 1053

Subject Initials: (b) (6)

Is Blank

### Urine Drug Screen

Was Urine Drug Screen Performed? ☒ Yes ☐ No

Date

DD/MMM/YYYY

22-OCT-2010

Urine Drug Screen Result

☐ Positive ☒ Negative

### Urine Pregnancy Test

Was Urine Pregnancy Test performed? ☐ Yes ☐ No ☒ NA, Male

Date

DD/MMM/YYYY

Urine Pregnancy Test Result

☐ Positive ☐ Negative

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Page Version No. PAGE\_10 (v1, 15-OCT-2010)

Document Number R340144013

## **Links to Discrepancy and Audit Sections**

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Document Number R340144213



R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

1053

Subject Initials:

(b) (6)

Is Blank

### Supine 12-Lead Electrocardiogram Report

Was ECG performed?	Date	Actual Time
<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	DD/MMM/YYYY	24-hour clock
	22-OCT-2010	10:53

Parameter	Unit	Result
Ventricular Heart Rate	beats/minute	64
PR Interval	milliseconds	160
QRS Duration	milliseconds	80
QT Interval	milliseconds	400
QTc Interval	milliseconds	412

ECG Interpretation:

☒ Normal ☐ Abnormal, NCS ☐ Abnormal, CS

Comments Regarding CS Findings:

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Document Number R341494913

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 2

Subject Number:

1053

Subject Initials:

(b) (6)

Is Blank

### Complete Physical Examination

Does the subject have any relevant findings?

☐ Yes ☒ No

Date

DD/MMM/YYYY

28-OCT-2010

Consider the following systems when performing the assessment:

01 General Appearance

05 Pulmonary

09 Lymphatic

02 Skin

06 Chest

10 Musculoskeletal

03 Ears, Eyes, Nose, Throat

07 Cardiovascular

11 Neurological

04 Head/Neck

08 Abdomen and Liver/Spleen

Code

Findings


Verified



Approved



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Document Number

R340144513

## **Links to Discrepancy and Audit Sections**

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R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Usual Brand Cigarette Pack Data

Date  
DD/MMM/YYYY

Parameter	Result
Usual Brand Name	<input type="text" value="MARLBORO GOLD PACI"/> (Note: include color designation if any)
Filtered	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Length	<input type="checkbox"/> 72 mm <input type="checkbox"/> 100 mm <input checked="" type="checkbox"/> 85 mm <input type="checkbox"/> 120 mm
Width	<input checked="" type="checkbox"/> Regular <input type="checkbox"/> Super Slims <input type="checkbox"/> Slims <input type="checkbox"/> Wides
Fire Standard Compliant?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Packaging	<input type="checkbox"/> Soft-pack <input checked="" type="checkbox"/> Hard-pack (box)

---

Oral Health Examination

Was Oral Health Examination performed? ☒ Yes ☐ No

Date  
DD/MMM/YYYY

Exam Determination	Result	If Yes, Please Describe
Evidence of Leukoplakia?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>
Evidence of Other Oral Keratosis?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>

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Page Version No. PAGE\_14 (v1, 15-OCT-2010)

Document Number

## OverFlow Section For Document Number R340144813

1 MARLBORO GOLD PACK

## **Links to Discrepancy and Audit Sections**

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R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 2

Subject Number:

1053

Subject Initials:

(b) (6)

Is Blank

Seated Vital Signs and HDYF? Inquiry

Did Subject Smoke Single Cigarette? ☒ Yes ☐ No

Were Measurements Collected 30-60 Minutes Following Cigarette? ☒ Yes ☐ No

Date	Actual Time Cigarette Smoked 24-hour clock	Actual Time Vitals Collected 24-hour clock	Was HDYF? question asked?
DD/MMM/YYYY			
28-OCT-2010	12:38	13:08	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

Parameter	Unit	Result
Systolic Blood Pressure	mmHg	138
Diastolic Blood Pressure	mmHg	98
Pulse	beats/minute	76
ECO	ppm	14

Urine Cotinine Screen

Not Applicable ☒

Date	Actual Time	NicCheck I Results	Not Done	Comments
DD/MMM/YYYY	24-hour clock	<input type="checkbox"/> Positive <input type="checkbox"/> Negative	<input type="checkbox"/>	

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Page Version No. PAGE\_15 (v1, 18-OCT-2010)

Document Number R340145413

## **Links to Discrepancy and Audit Sections**

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R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 2

Subject Number:

1053

Subject Initials:

(b) (6)

Is Blank

### Randomization

Date

DD/MMM/YYYY

Randomization Number

Randomized Group

05-NOV-2010

1053

☐ SNUS

☐ Strips

☒ Dual Use of UB Cigarettes and SNUS

☐ Sticks

☐ Tobacco Abstinence

☐ Orbs

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Page Version No. PAGE\_16 (v1, 15-OCT-2010)

Document Number R341498313

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

#### Seated Vital Signs and HDYF? Inquiry

Were vital signs collected? ☒ Yes ☐ No

Date  
DD/MMM/YYYY

Actual Time  
24-hour clock

Was HDYF?  
question asked?

☐ Yes ☒ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

Diastolic Blood Pressure

mmHg

Pulse

beats/minute

Respiratory Rate

breaths/minute

Oral Temperature

°C

#### Urine Drug Screen

Was Urine Drug Screen Performed? ☒ Yes ☐ No

Date  
DD/MMM/YYYY

Urine Drug Screen Result

☐ Positive ☒ Negative

#### Urine Pregnancy Test

Was Urine Pregnancy Test performed? ☐ Yes ☐ No ☒ NA, Male

Date  
DD/MMM/YYYY

Urine Pregnancy Test Result

☐ Positive ☐ Negative

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Page Version No. PAGE\_17 (v1, 15-OCT-2010)

Document Number

## **Links to Discrepancy and Audit Sections**

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R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name BASELINE, DAY -1

Subject Number: 1053

Subject Initials: (b) (6)

Is Blank

#### Seated Vital Signs and HDYF? Inquiry

Were vital signs collected? ☒ Yes ☐ No

Date  
DD/MMM/YYYY

10-NOV-2010

Actual Time  
24-hour clock

08:08

Was HDYF?  
question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

132

Diastolic Blood Pressure

mmHg

85

Pulse

beats/minute

73

Respiratory Rate

breaths/minute

18

Oral Temperature

°C

36.7

#### Blood Collection for COHb

Date

DD/MMM/YYYY

Scheduled Timepoint

Actual Time

24-hour clock

Not

Done

Comments

10-NOV-2010

22:00

22:08

☐

#### Expired Carbon Monoxide

Date

DD/MMM/YYYY

Scheduled Timepoint

Actual Time

24-hour clock

ECO Level

(ppm)

% COHb

Not Done

Comments

10-NOV-2010

07:00

07:10

4

1.3

☐

10-NOV-2010

12:00

12:11

15

3.0

☐

10-NOV-2010

22:00

22:10

23

4.3

☐

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Page Version No. PAGE\_18 (v1, 15-OCT-2010)

Document Number R341502913

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name BASELINE, DAY -1

Subject Number: 1053

Subject Initials: (b) (6)

Is Blank

UB Cigarette Dispensation/Collection

Seq	Date DD/MMM/YYYY	Time UB Dispensed 24-hour clock	Time UB Returned 24-hour clock	Cigarette Butt Length mm	Mouth-End Filter Cut for YIU?		If No, Comment
1	10-NOV-2010	07:12	07:18	36	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
2	10-NOV-2010	08:11	08:22	38	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
3	10-NOV-2010	09:21	09:34	38	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
4	10-NOV-2010	11:16	11:24	37	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
5	10-NOV-2010	11:38	11:43	37	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
6	10-NOV-2010	12:40	12:48	38	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
7	10-NOV-2010	13:28	13:37	39	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
8	10-NOV-2010	14:48	14:53	40	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
9	10-NOV-2010	16:00	16:07	37	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
10	10-NOV-2010	17:07	17:11	37	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
11	10-NOV-2010	18:39	18:47	37	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
12	10-NOV-2010	20:52	21:00	37	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
13	10-NOV-2010	21:38	21:41	37	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
14	10-NOV-2010	22:41	22:48	35	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	

End-of-Day Daily Composited YIU Filter Tip Disposition

Date DD/MMM/YYYY	End-of-Day Total Tip Count	Time of Day Daily YIU Frozen (-70C) 24-hour clock	Does Count Agree with Usage Log-Comment
10-NOV-2010	14	23:41	YES

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Document Number R341503013

R341503113

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name BASELINE, DAY -1

Subject Number: 1053

Subject Initials: (b) (6)

Is Blank

### Urine Collection

Scheduled Timepoint	Start Date/Time	Stop Date/Time	Total	Not	Comments
	DD/MMM/YYYY	DD/MMM/YYYY	Volume		
-24 HOURS TO 0 HOUR	24-hour clock	24-hour clock	mL	Done	
	10-NOV-2010	11-NOV-2010	1720	<input type="checkbox"/>	
	06:48	07:08			

### Plasma Nicotine/Cotinine and Thiocyanate Analytical Sample

Date	Scheduled Timepoint	Actual Time	Not	Comments
DD/MMM/YYYY		24-hour clock	Done	
10-NOV-2010	07:00	07:08	<input type="checkbox"/>	
10-NOV-2010	12:00	12:08	<input type="checkbox"/>	
10-NOV-2010	22:00	22:08	<input type="checkbox"/>	

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Document Number R341503213

## **Links to Discrepancy and Audit Sections**

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R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name BASELINE, DAY -1

Subject Number: 1053

Subject Initials: (b) (6)

Is Blank

Fecal Collection

Not Applicable NOTCHECK

Scheduled Timepoint	Collection Date/Time		Weight g	Not Done	Comments
	DD/MMM/YYYY	24-hour clock			
DAY -1	10-NOV-2010	10:55	221.3	<input type="checkbox"/>	
DAY -1	10-NOV-2010	15:56	205.3	<input type="checkbox"/>	
DAY -1	10-NOV-2010	20:45	121.0	<input type="checkbox"/>	
				<input type="checkbox"/>	
				<input type="checkbox"/>	
				<input type="checkbox"/>	
				<input type="checkbox"/>	

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_21 (v1, 15-OCT-2010)

Document Number R341503313

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name BASELINE, DAY -1

Subject Number: 1053

Subject Initials: (b) (6)

Is Blank

### Questionnaires

Date of Assessment

DD/MMM/YYYY

10-NOV-2010

Scheduled Timepoint

19:00

Questionnaire

B-QSU

MNWS

Was Questionnaire Administered?

☒ Yes ☐ No

☒ Yes ☐ No

---

### Maximum Use Level

Date

DD/MMM/YYYY

10-NOV-2010

Maximum Product Use

Allowed Per Day:

6

40% UB for Dual Use subjects:

6

☐ NA, Not Dual Use group

Comments

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_22 (v1, 02-NOV-2010)

Document Number R341503413

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Seated Vital Signs and HDYF? Inquiry

Were vital signs collected? ☒ Yes ☐ No

Date  
DD/MMM/YYYY

Actual Time  
24-hour clock

Was HDYF?  
question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

Diastolic Blood Pressure

mmHg

Pulse

beats/minute

Respiratory Rate

breaths/minute

Oral Temperature

°C

Assessment of Daily Alcohol Consumption

Was Daily Alcohol Consumption Rate Assessed?

☒ Yes ☐ No ☐ NA, Not a Drinker

Date of Assessment  
DD/MMM/YYYY

If Yes, Specify Daily Amount

12-ounce serving of Ultralight Beer

6-ounce serving of White or Rose Wine

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_23 (v1, 15-OCT-2010)

Document Number

## **Links to Discrepancy and Audit Sections**

[Click here to navigate to audit history for this CRF](#)

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

SNUS Dispensation/Collection

NA, Not SNUS or Dual Use group

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Flavor Dispensed	Time Returned 24-hour clock
<input type="text" value="1"/>	<input type="text" value="11-NOV-2010"/>	<input type="text" value="11:38"/>	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	<input type="text" value="12:06"/>
<input type="text" value="2"/>	<input type="text" value="11-NOV-2010"/>	<input type="text" value="19:34"/>	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	<input type="text" value="20:00"/>
<input type="text" value="3"/>	<input type="text" value="11-NOV-2010"/>	<input type="text" value="21:38"/>	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	<input type="text" value="22:16"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_24 (v1, 21-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 1

Subject Number:

1053

Subject Initials:

(b) (6)

Is Blank

SNUS Dispensation/Collection (Continued)

NA, Not SNUS or Dual Use group

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Flavor Dispensed	Time Returned 24-hour clock
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	

End-of-Day Daily Composited SNUS Use

NA, Not SNUS or Dual Use group

NOTCHECK

Date DD/MMM/YYYY	End-of-Day Total SNUS Count	Time of Day Frozen (-70C) 24-hour clock	Does Count Agree with Usage Log-Comment
11-NOV-2010	3	23:03	YES

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_25 (v1, 21-OCT-2010)

Document Number

R341616713

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 1

Subject Number:

1053

Subject Initials:

(b) (6)

Is Blank

Sticks Dispensation/Collection

NA, Not Sticks group

CHECKED

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Completely Consumed?	If No, Length Returned (mm)?
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_26 (v1, 15-OCT-2010)

Document Number

R341617313

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 1

Subject Number:

1053

Subject Initials:

(b) (6)

Is Blank

Sticks Dispensation/Collection (Continued)

NA, Not Sticks group

CHECKED

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Completely Consumed?	If No, Length Returned (mm)?
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	

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Page Version No. PAGE\_27 (v1, 15-OCT-2010)

Document Number

R341617413



R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Strips Dispensation/Collection

NA, Not Strips group

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Completely Consumed?	If No, then Comment
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_28 (v1, 15-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Strips Dispensation/Collection (Continued)

NA, Not Strips group

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Completely Consumed?	If No, then Comment
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_29 (v1, 15-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Orbs Dispensation/Collection

NA, Not Orbs Group

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Completely Consumed?	If No, then Comment
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_30 (v1, 19-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Orbs Dispensation/Collection (Continued)

NA, Not Orbs Group

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Completely Consumed?	If No, then Comment
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_31 (v1, 19-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

UB Cigarette Dispensation/Collection

NA, Not Dual Use group

Seq	Date DD/MMM/YYYY	Time UB Dispensed 24-hour clock	Time UB Returned 24-hour clock	Cigarette Butt Length mm	Mouth-End Filter Cut for YIU?		If No, Comment
1	11-NOV-2010	09:22	09:27	37	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
2	11-NOV-2010	13:22	13:30	39	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
3	11-NOV-2010	15:53	15:58	35	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
4	11-NOV-2010	18:29	18:35	34	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
5	11-NOV-2010	21:10	21:21	36	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
6	11-NOV-2010	22:31	22:39	37	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	

End-of-Day Daily Composited YIU Filter Tip Disposition

NA, Not Dual Use group

Date DD/MMM/YYYY	End-of-Day Total Tip Count	Time of Day Daily YIU Frozen (-70C) 24-hour clock	Does Count Agree with Usage Log-Comment
11-NOV-2010	6	23:03	YES

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_32 (v1, 18-OCT-2010)

Document Number



R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 1

Subject Number:

1053

Subject Initials:

(b) (6)

Is Blank

### Urine Collection

Scheduled Timepoint	Start Date/Time	Stop Date/Time	Total	Not	Comments
	DD/MMM/YYYY	DD/MMM/YYYY	Volume		
24-hour clock	24-hour clock	24-hour clock	mL	Done	
0 HOUR TO 24 HOURS	11-NOV-2010	12-NOV-2010	2800	<input type="checkbox"/>	
	07:08	07:08			

### Plasma Nicotine/Cotinine and Thiocyanate Analytical Sample

Date	Scheduled Timepoint	Actual Time	Not	Comments
DD/MMM/YYYY		24-hour clock	Done	
11-NOV-2010	07:00	07:08	<input type="checkbox"/>	
11-NOV-2010	12:00	12:08	<input type="checkbox"/>	
11-NOV-2010	22:00	22:08	<input type="checkbox"/>	

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_33 (v1, 15-OCT-2010)

Document Number R341619513

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 1

Subject Number:

1053

Subject Initials:

(b) (6)

Is Blank

### Blood Collection for COHb

Date

DD/MMM/YYYY

Scheduled Timepoint

Actual Time

24-hour clock

Not

Done

Comments

11-NOV-2010

22:00

22:08

☐

### Expired Carbon Monoxide

Date

DD/MMM/YYYY

Scheduled Timepoint

Actual Time

24-hour clock

ECO Level

(ppm)

% COHb

Not Done

Comments

11-NOV-2010

07:00

07:09

8

1.9

☐

11-NOV-2010

12:00

12:09

7

1.8

☐

11-NOV-2010

22:00

22:09

12

2.6

☐

### Questionnaires

Date of Assessment

DD/MMM/YYYY

Scheduled Timepoint

11-NOV-2010

19:00

Questionnaire

Was Questionnaire Administered?

B-QSU

☒ Yes ☐ No

MNWS

☒ Yes ☐ No

Verified

☒

Approved

☒

Locked

☒

Frozen

☒

Page Version No. PAGE\_34 (v1, 02-NOV-2010)

Document Number

R341619813



R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Seated Vital Signs and HDYF? Inquiry

Were vital signs collected? ☒ Yes ☐ No

Date  
DD/MMM/YYYY

Actual Time  
24-hour clock

Was HDYF?  
question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

Diastolic Blood Pressure

mmHg

Pulse

beats/minute

Respiratory Rate

breaths/minute

Oral Temperature

°C

Assessment of Daily Alcohol Consumption

Was Daily Alcohol Consumption Rate Assessed?

☒ Yes ☐ No ☐ NA, Not a Drinker

Date of Assessment  
DD/MMM/YYYY

If Yes, Specify Daily Amount

12-ounce serving of Ultralight Beer

6-ounce serving of White or Rose Wine

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_35 (v1, 15-OCT-2010)

Document Number

## **Links to Discrepancy and Audit Sections**

[Click here to navigate to audit history for this CRF](#)

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 2

Subject Number:

1053

Subject Initials:

(b) (6)

Is Blank

SNUS Dispensation/Collection

NA, Not SNUS or Dual Use group

NOTCHECK

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Flavor Dispensed	Time Returned 24-hour clock
1	12-NOV-2010	11:40	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	12:25
2	12-NOV-2010	14:59	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	15:40
3	12-NOV-2010	20:43	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	21:00
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	

Verified



Approved



Locked



Frozen



Page Version No. PAGE\_36 (v1, 21-OCT-2010)

Document Number

R341620113

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

SNUS Dispensation/Collection (Continued)

NA, Not SNUS or Dual Use group

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Flavor Dispensed	Time Returned 24-hour clock
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>

End-of-Day Daily Composited SNUS Use

NA, Not SNUS or Dual Use group

Date DD/MMM/YYYY	End-of-Day Total SNUS Count	Time of Day Frozen (-70C) 24-hour clock	Does Count Agree with Usage Log-Comment
<input type="text" value="12-NOV-2010"/>	<input type="text" value="3"/>	<input type="text" value="23 : 24"/>	<input type="text" value="YES"/>

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_37 (v1, 21-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 2

Subject Number:

1053

Subject Initials:

(b) (6)

Is Blank

Sticks Dispensation/Collection

NA, Not Sticks group

CHECKED

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Completely Consumed?	If No, Length Returned (mm)?
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
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			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_38 (v1, 15-OCT-2010)

Document Number

R341621313

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Sticks Dispensation/Collection (Continued)

NA, Not Sticks group

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Completely Consumed?	If No, Length Returned (mm)?
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_39 (v1, 15-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Strips Dispensation/Collection

NA, Not Strips group

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Completely Consumed?	If No, then Comment
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_40 (v1, 15-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Strips Dispensation/Collection (Continued)

NA, Not Strips group

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Completely Consumed?	If No, then Comment
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_41 (v1, 15-OCT-2010)

Document Number



R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Orbs Dispensation/Collection

NA, Not Orbs Group

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Completely Consumed?	If No, then Comment
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
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<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_42 (v1, 19-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Orbs Dispensation/Collection (Continued)

NA, Not Orbs Group

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Completely Consumed?	If No, then Comment
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_43 (v1, 19-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

UB Cigarette Dispensation/Collection

NA, Not Dual Use group

Seq	Date DD/MMM/YYYY	Time UB Dispensed 24-hour clock	Time UB Returned 24-hour clock	Cigarette Butt Length mm	Mouth-End Filter Cut for YIU?	If No, Comment
1	12-NOV-2010	09:18	09:23	38	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
2	12-NOV-2010	13:25	13:30	37	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
3	12-NOV-2010	16:47	16:53	37	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
4	12-NOV-2010	18:46	18:52	36	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
5	12-NOV-2010	21:32	21:53	38	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
6	12-NOV-2010	22:31	22:37	38	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	

End-of-Day Daily Composited YIU Filter Tip Disposition

NA, Not Dual Use group

Date DD/MMM/YYYY	End-of-Day Total Tip Count	Time of Day Daily YIU Frozen (-70C) 24-hour clock	Does Count Agree with Usage Log-Comment
12-NOV-2010	6	23:23	YES

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_44 (v1, 18-OCT-2010)

Document Number

R341622813

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Seated Vital Signs and HDYF? Inquiry

Were vital signs collected? ☒ Yes ☐ No

Date  
DD/MMM/YYYY

Actual Time  
24-hour clock

Was HDYF?  
question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

Diastolic Blood Pressure

mmHg

Pulse

beats/minute

Respiratory Rate

breaths/minute

Oral Temperature

°C

Assessment of Daily Alcohol Consumption

Was Daily Alcohol Consumption Rate Assessed?

☒ Yes ☐ No ☐ NA, Not a Drinker

Date of Assessment  
DD/MMM/YYYY

If Yes, Specify Daily Amount

12-ounce serving of Ultralight Beer

6-ounce serving of White or Rose Wine

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_45 (v1, 15-OCT-2010)

Document Number

## **Links to Discrepancy and Audit Sections**

[Click here to navigate to audit history for this CRF](#)

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 3

Subject Number:

1053

Subject Initials:

(b) (6)

Is Blank

SNUS Dispensation/Collection

NA, Not SNUS or Dual Use group

NOTCHECK

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Flavor Dispensed	Time Returned 24-hour clock
1	13-NOV-2010	11:38	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	12:05
2	13-NOV-2010	15:18	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	15:47
3	13-NOV-2010	20:12	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	20:39
4	13-NOV-2010	21:38	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	22:05
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	

Verified



Approved



Locked



Frozen



Page Version No. PAGE\_46 (v1, 21-OCT-2010)

Document Number

R341623013

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

SNUS Dispensation/Collection (Continued)

NA, Not SNUS or Dual Use group

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Flavor Dispensed	Time Returned 24-hour clock
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>

End-of-Day Daily Composited SNUS Use

NA, Not SNUS or Dual Use group

Date DD/MMM/YYYY	End-of-Day Total SNUS Count	Time of Day Frozen (-70C) 24-hour clock	Does Count Agree with Usage Log-Comment
<input type="text" value="13-NOV-2010"/>	<input type="text" value="4"/>	<input type="text" value="23:10"/>	<input type="text" value="YES"/>

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_47 (v1, 21-OCT-2010)

Document Number



R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 3

Subject Number:

1053

Subject Initials:

(b) (6)

Is Blank

Sticks Dispensation/Collection

NA, Not Sticks group

CHECKED

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Completely Consumed?	If No, Length Returned (mm)?
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_48 (v1, 15-OCT-2010)

Document Number

R341623513

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 3

Subject Number:

1053

Subject Initials:

(b) (6)

Is Blank

Sticks Dispensation/Collection (Continued)

NA, Not Sticks group

CHECKED

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Completely Consumed?	If No, Length Returned (mm)?
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_49 (v1, 15-OCT-2010)

Document Number R341623613

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Strips Dispensation/Collection

NA, Not Strips group

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Completely Consumed?	If No, then Comment
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_50 (v1, 15-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Strips Dispensation/Collection (Continued)

NA, Not Strips group

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Completely Consumed?	If No, then Comment
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_51 (v1, 15-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Orbs Dispensation/Collection

NA, Not Orbs Group

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Completely Consumed?	If No, then Comment
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_52 (v1, 19-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Orbs Dispensation/Collection (Continued)

NA, Not Orbs Group

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Completely Consumed?	If No, then Comment
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_53 (v1, 19-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 3

Subject Number: 1053

Subject Initials: (b) (6)

Is Blank

UB Cigarette Dispensation/Collection

NA, Not Dual Use group NOTCHECK

Seq	Date DD/MMM/YYYY	Time UB Dispensed 24-hour clock	Time UB Returned 24-hour clock	Cigarette Butt Length mm	Mouth-End Filter Cut for YIU?	If No, Comment
1	13-NOV-2010	09:27	09:36	36	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
2	13-NOV-2010	13:45	13:53	35	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
3	13-NOV-2010	16:43	16:46	34	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
4	13-NOV-2010	18:37	18:41	34	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
5	13-NOV-2010	21:16	21:20	38	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
6	13-NOV-2010	22:32	22:35	40	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	

End-of-Day Daily Composited YIU Filter Tip Disposition

NA, Not Dual Use group NOTCHECK

Date DD/MMM/YYYY	End-of-Day Total Tip Count	Time of Day Daily YIU Frozen (-70C) 24-hour clock	Does Count Agree with Usage Log-Comment
13-NOV-2010	6	23:10	YES

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_54 (v1, 18-OCT-2010)

Document Number R341624513

## **Links to Discrepancy and Audit Sections**

[Click here to navigate to audit history for this CRF](#)

[Click here to navigate to discrepancy details for this CRF](#)





R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

### Urine Collection

Scheduled Timepoint	Start Date/Time	Stop Date/Time	Total	Not	Comments
	DD/MMM/YYYY 24-hour clock	DD/MMM/YYYY 24-hour clock	Volume mL		
48 HOURS TO 72 HOURS	<input type="text" value="13-NOV-2010"/>	<input type="text" value="14-NOV-2010"/>	<input type="text" value="2500"/>	<input type="checkbox"/>	<input type="text"/>
	<input type="text" value="06:48"/>	<input type="text" value="07:08"/>			

### Plasma Nicotine/Cotinine and Thiocyanate Analytical Sample

Date	Scheduled Timepoint	Actual Time	Not	Comments
DD/MMM/YYYY		24-hour clock	Done	
<input type="text" value="13-NOV-2010"/>	<input type="text" value="07:00"/>	<input type="text" value="07:08"/>	<input type="checkbox"/>	<input type="text"/>
<input type="text" value="13-NOV-2010"/>	<input type="text" value="12:00"/>	<input type="text" value="12:08"/>	<input type="checkbox"/>	<input type="text"/>
<input type="text" value="13-NOV-2010"/>	<input type="text" value="22:00"/>	<input type="text" value="22:08"/>	<input type="checkbox"/>	<input type="text"/>

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_55 (v1, 15-OCT-2010)

Document Number

## **Links to Discrepancy and Audit Sections**

[Click here to navigate to audit history for this CRF](#)

[Click here to navigate to discrepancy details for this CRF](#)

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 3

Subject Number:

1053

Subject Initials:

(b) (6)

Is Blank

### Blood Collection for COHb

Date

DD/MMM/YYYY

Scheduled Timepoint

Actual Time

24-hour clock

Not

Done

Comments

13-NOV-2010

22:00

22:08

☐

### Expired Carbon Monoxide

Date

DD/MMM/YYYY

Scheduled Timepoint

Actual Time

24-hour clock

ECO Level

(ppm)

% COHb

Not Done

Comments

13-NOV-2010

07:00

07:10

7

1.8

☐

13-NOV-2010

12:00

12:09

8

1.9

☐

13-NOV-2010

22:00

22:09

13

2.7

☐

### Questionnaires

Date of Assessment

DD/MMM/YYYY

Scheduled Timepoint

13-NOV-2010

19:00

Questionnaire

Was Questionnaire Administered?

B-QSU

☒ Yes ☐ No

MNWS

☒ Yes ☐ No

Verified

☒

Approved

☒

Locked

☒

Frozen

☒

Page Version No. PAGE\_56 (v1, 02-NOV-2010)

Document Number

R341626213

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 4

Subject Number:

1053

Subject Initials:

(b) (6)

Is Blank

Seated Vital Signs and HDYF? Inquiry

Were vital signs collected? ☒ Yes ☐ No

Date  
DD/MMM/YYYY

14-NOV-2010

Actual Time  
24-hour clock

08:08

Was HDYF?  
question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

131

Diastolic Blood Pressure

mmHg

90

Pulse

beats/minute

56

Respiratory Rate

breaths/minute

14

Oral Temperature

°C

36.8

Assessment of Daily Alcohol Consumption

Was Daily Alcohol Consumption Rate Assessed?

☒ Yes ☐ No ☐ NA, Not a Drinker

Date of Assessment  
DD/MMM/YYYY

14-NOV-2010

If Yes, Specify Daily Amount

02

12-ounce serving of Ultralight Beer

00

6-ounce serving of White or Rose Wine

Verified

☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_57 (v1, 15-OCT-2010)

Document Number

R341522113

## **Links to Discrepancy and Audit Sections**

[Click here to navigate to audit history for this CRF](#)

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 4

Subject Number:

1053

Subject Initials:

(b) (6)

Is Blank

SNUS Dispensation/Collection

NA, Not SNUS or Dual Use group

NOTCHECK

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Flavor Dispensed	Time Returned 24-hour clock
1	14-NOV-2010	11:43	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	12:34
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_58 (v1, 21-OCT-2010)

Document Number

R341626513

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

SNUS Dispensation/Collection (Continued)

NA, Not SNUS or Dual Use group

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Flavor Dispensed	Time Returned 24-hour clock
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>

End-of-Day Daily Composited SNUS Use

NA, Not SNUS or Dual Use group

Date DD/MMM/YYYY	End-of-Day Total SNUS Count	Time of Day Frozen (-70C) 24-hour clock	Does Count Agree with Usage Log-Comment
<input type="text" value="14-NOV-2010"/>	<input type="text" value="1"/>	<input type="text" value="23:06"/>	<input type="text" value="YES"/>

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_59 (v1, 21-OCT-2010)

Document Number



R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 4

Subject Number:

1053

Subject Initials:

(b) (6)

Is Blank

Sticks Dispensation/Collection

NA, Not Sticks group

CHECKED

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Completely Consumed?	If No, Length Returned (mm)?
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	

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Page Version No. PAGE\_60 (v1, 15-OCT-2010)

Document Number

R341626913

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Sticks Dispensation/Collection (Continued)

NA, Not Sticks group

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Completely Consumed?	If No, Length Returned (mm)?
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_61 (v1, 15-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Strips Dispensation/Collection

NA, Not Strips group

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Completely Consumed?	If No, then Comment
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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Page Version No. PAGE\_62 (v1, 15-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Strips Dispensation/Collection (Continued)

NA, Not Strips group

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Completely Consumed?	If No, then Comment
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_63 (v1, 15-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Orbs Dispensation/Collection

NA, Not Orbs Group

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Completely Consumed?	If No, then Comment
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_64 (v1, 19-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Orbs Dispensation/Collection (Continued)

NA, Not Orbs Group

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Completely Consumed?	If No, then Comment
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_65 (v1, 19-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 4

Subject Number:

1053

Subject Initials:

(b) (6)

Is Blank

UB Cigarette Dispensation/Collection

NA, Not Dual Use group

NOTCHECK

Seq	Date DD/MMM/YYYY	Time UB Dispensed 24-hour clock	Time UB Returned 24-hour clock	Cigarette Butt Length mm	Mouth-End Filter Cut for YIU?		If No, Comment
1	14-NOV-2010	09:21	09:26	37	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
2	14-NOV-2010	13:30	13:35	38	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
3	14-NOV-2010	15:53	15:58	39	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
4	14-NOV-2010	18:38	18:43	37	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	

End-of-Day Daily Composited YIU Filter Tip Disposition

NA, Not Dual Use group

NOTCHECK

Date DD/MMM/YYYY	End-of-Day Total Tip Count	Time of Day Daily YIU Frozen (-70C) 24-hour clock	Does Count Agree with Usage Log-Comment
14-NOV-2010	4	23:06	YES

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Page Version No. PAGE\_66 (v1, 18-OCT-2010)

Document Number R341628113

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☒

UB Cigarette Dispensation/Collection

NA, Not Dual Use group

Seq	Date DD/MMM/YYYY	Time UB Dispensed 24-hour clock	Time UB Returned 24-hour clock	Cigarette Butt Length mm	Mouth-End Filter Cut for YIU?		If No, Comment
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	

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Page Version No. PAGE\_66.1 (v1, 18-NOV-2010)

Document Number



R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 1053

Subject Initials: (b) (6)

Is Blank

Seated Vital Signs and HDYF? Inquiry

Were vital signs collected? ☒ Yes ☐ No

Date  
DD/MMM/YYYY

15-NOV-2010

Actual Time  
24-hour clock

08:09

Was HDYF?  
question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

130

Diastolic Blood Pressure

mmHg

90

Pulse

beats/minute

58

Respiratory Rate

breaths/minute

12

Oral Temperature

°C

36.4

Assessment of Daily Alcohol Consumption

Was Daily Alcohol Consumption Rate Assessed?

☒ Yes ☐ No ☐ NA, Not a Drinker

Date of Assessment  
DD/MMM/YYYY

15-NOV-2010

If Yes, Specify Daily Amount

02 12-ounce serving of Ultralight Beer

00 6-ounce serving of White or Rose Wine

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Page Version No. PAGE\_67 (v1, 15-OCT-2010)

Document Number R341522213

## **Links to Discrepancy and Audit Sections**

[Click here to navigate to audit history for this CRF](#)

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 1053

Subject Initials: (b) (6)

Is Blank

SNUS Dispensation/Collection

NA, Not SNUS or Dual Use group NOTCHECK

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Flavor Dispensed	Time Returned 24-hour clock
1	15-NOV-2010	11:38	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	12:04
2	15-NOV-2010	15:43	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	16:16
3	15-NOV-2010	21:38	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	22:11
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	

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Page Version No. PAGE\_68 (v1, 21-OCT-2010)

Document Number R341629013

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 1053

Subject Initials: (b) (6)

Is Blank

SNUS Dispensation/Collection (Continued)

NA, Not SNUS or Dual Use group

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Flavor Dispensed	Time Returned 24-hour clock
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	

End-of-Day Daily Composited SNUS Use

NA, Not SNUS or Dual Use group NOTCHECK

Date DD/MMM/YYYY	End-of-Day Total SNUS Count	Time of Day Frozen (-70C) 24-hour clock	Does Count Agree with Usage Log-Comment
15-NOV-2010	3	23:26	YES

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Page Version No. PAGE\_69 (v1, 21-OCT-2010)

Document Number R341629213



R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 5/EARLY TERM

Subject Number:

1053

Subject Initials:

(b) (6)

Is Blank

Sticks Dispensation/Collection (Continued)

NA, Not Sticks group

CHECKED

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Completely Consumed?	If No, Length Returned (mm)?
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	

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Page Version No. PAGE\_71 (v1, 15-OCT-2010)

Document Number

R341629613

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 1053

Subject Initials: (b) (6)

Is Blank

Strips Dispensation/Collection

NA, Not Strips group CHECKED

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Completely Consumed?	If No, then Comment
			<input type="checkbox"/> 1 Strip	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Strips	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Strip	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Strips	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Strip	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Strips	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Strip	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Strips	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Strip	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Strips	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Strip	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Strips	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Strip	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Strips	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Strip	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Strips	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Strip	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Strips	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Strip	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Strips	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Strip	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Strips	<input type="checkbox"/> No	

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Page Version No. PAGE\_72 (v1, 15-OCT-2010)

Document Number R341629713

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 1053

Subject Initials: (b) (6)

Is Blank

Strips Dispensation/Collection (Continued)

NA, Not Strips group CHECKED

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Completely Consumed?	If No, then Comment
			<input type="checkbox"/> 1 Strip	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Strips	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Strip	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Strips	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Strip	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Strips	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Strip	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Strips	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Strip	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Strips	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Strip	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Strips	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Strip	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Strips	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Strip	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Strips	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Strip	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Strips	<input type="checkbox"/> No	

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Page Version No. PAGE\_73 (v1, 15-OCT-2010)

Document Number R341629913



R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 1053

Subject Initials: (b) (6)

Is Blank

Orbs Dispensation/Collection

NA, Not Orbs Group CHECKED

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Completely Consumed?	If No, then Comment
			<input type="checkbox"/> 1 Orb	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Orbs	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Orb	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Orbs	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Orb	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Orbs	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Orb	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Orbs	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Orb	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Orbs	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Orb	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Orbs	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Orb	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Orbs	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Orb	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Orbs	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Orb	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Orbs	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Orb	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Orbs	<input type="checkbox"/> No	

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Page Version No. PAGE\_74 (v1, 19-OCT-2010)

Document Number R341630113

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 1053

Subject Initials: (b) (6)

Is Blank

Orbs Dispensation/Collection (Continued)

NA, Not Orbs Group CHECKED

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Completely Consumed?	If No, then Comment
			<input type="checkbox"/> 1 Orb	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Orbs	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Orb	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Orbs	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Orb	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Orbs	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Orb	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Orbs	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Orb	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Orbs	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Orb	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Orbs	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Orb	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Orbs	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Orb	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Orbs	<input type="checkbox"/> No	

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Page Version No. PAGE\_75 (v1, 19-OCT-2010)

Document Number R341630313

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 1053

Subject Initials: (b) (6)

Is Blank

UB Cigarette Dispensation/Collection

NA, Not Dual Use group NOTCHECK

Seq	Date DD/MMM/YYYY	Time UB Dispensed 24-hour clock	Time UB Returned 24-hour clock	Cigarette Butt Length mm	Mouth-End Filter Cut for YIU?		If No, Comment
1	15-NOV-2010	09:15	09:19	35	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
2	15-NOV-2010	13:34	13:39	37	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
3	15-NOV-2010	17:05	17:10	34	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
4	15-NOV-2010	18:35	18:41	36	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
5	15-NOV-2010	21:12	21:19	35	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
6	15-NOV-2010	22:36	22:41	37	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	

End-of-Day Daily Composited YIU Filter Tip Disposition

NA, Not Dual Use group NOTCHECK

Date DD/MMM/YYYY	End-of-Day Total Tip Count	Time of Day Daily YIU Frozen (-70C) 24-hour clock	Does Count Agree with Usage Log-Comment
15-NOV-2010	6	23:25	YES

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_76 (v1, 18-OCT-2010)

Document Number R341630713



R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 1053

Subject Initials: (b) (6)

Is Blank

### Urine Collection

Scheduled Timepoint	Start Date/Time	Stop Date/Time	Total	Not	Comments
	DD/MMM/YYYY 24-hour clock	DD/MMM/YYYY 24-hour clock	Volume mL		
96 HOURS TO 120 HOURS	15-NOV-2010 06:48	16-NOV-2010 07:08	2000	<input type="checkbox"/>	

### Plasma Nicotine/Cotinine and Thiocyanate Analytical Sample

Date	Scheduled Timepoint	Actual Time	Not	Comments
DD/MMM/YYYY		24-hour clock	Done	
15-NOV-2010	07:00	07:08	<input type="checkbox"/>	
15-NOV-2010	12:00	12:08	<input type="checkbox"/>	
15-NOV-2010	22:00	22:08	<input type="checkbox"/>	

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_77 (v1, 15-OCT-2010)

Document Number R341631613

## **Links to Discrepancy and Audit Sections**

[Click here to navigate to audit history for this CRF](#)

[Click here to navigate to discrepancy details for this CRF](#)

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 1053

Subject Initials: (b) (6)

Is Blank

### Fecal Collection

Not Applicable NOTCHECK

Scheduled Timepoint	Collection Date/Time DD/MMM/YYYY 24-hour clock	Weight g	Not Done	Comments
DAY 5	15-NOV-2010 06:56	205.1	<input type="checkbox"/>	
DAY 5			<input checked="" type="checkbox"/>	
DAY 5			<input checked="" type="checkbox"/>	
DAY 5			<input checked="" type="checkbox"/>	
DAY 5			<input checked="" type="checkbox"/>	
DAY 5			<input checked="" type="checkbox"/>	
DAY 5			<input checked="" type="checkbox"/>	

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Page Version No. PAGE\_78 (v1, 15-OCT-2010)

Document Number R341631813

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 1053

Subject Initials: (b) (6)

Is Blank

#### Blood Collection for COHb

Date DD/MMM/YYYY	Scheduled Timepoint	Actual Time 24-hour clock	Not Done	Comments
15-NOV-2010	22:00	22:08	<input type="checkbox"/>	

#### Expired Carbon Monoxide

Date DD/MMM/YYYY	Scheduled Timepoint	Actual Time 24-hour clock	ECO Level (ppm)	% COHb	Not Done	Comments
15-NOV-2010	07:00	07:11	4	1.3	<input type="checkbox"/>	
15-NOV-2010	12:00	12:09	7	1.8	<input type="checkbox"/>	
15-NOV-2010	22:00	22:10	13	2.7	<input type="checkbox"/>	

#### Questionnaires

Date of Assessment

DD/MMM/YYYY

15-NOV-2010

Scheduled Timepoint

19:00

Questionnaire

B-QSU

MNWS

Exit - Product Attributes

Was Questionnaire Administered?

☒ Yes ☐ No

☒ Yes ☐ No

☒ Yes ☐ No

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_79 (v1, 02-NOV-2010)

Document Number R341632213



R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 1053

Subject Initials: (b) (6)

Is Blank

#### Laboratory Evaluations

Were the scheduled laboratory samples obtained?

☒ Yes ☐ No (Specify samples not done, reason):

Date

DD/MMM/YYYY

15-NOV-2010

Evaluations: Chem-19 (fasted at least 8 hours), CBC, and Urinalysis

Requisition Number 1:

Y245565

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

Requisition Number 4 (if applicable):

Requisition Number 5 (if applicable):

Were there any clinically significant labs? ☐ Yes (specify below) ☒ No

Requisition Number

Test Name

Test Code ID


#### Urine Pregnancy Test

Was Urine Pregnancy Test performed? ☐ Yes ☐ No ☒ NA, Male

Date

DD/MMM/YYYY

Urine Pregnancy Test Result

☐ Positive ☐ Negative

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_80 (v1, 18-OCT-2010)

Document Number R341632713

## **Links to Discrepancy and Audit Sections**

[Click here to navigate to audit history for this CRF](#)

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 1053

Subject Initials: (b) (6)

Is Blank

### Abbreviated Physical Examination

Does the subject have any relevant findings?

☐ Yes ☒ No

Date

DD/MMM/YYYY

15-NOV-2010

Consider the following systems when performing the assessment:

01 General Appearance

06 Chest

02 Skin

07 Cardiovascular

05 Pulmonary

08 Abdomen and Liver/Spleen

Code

Findings


Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_81 (v1, 15-OCT-2010)

Document Number R341633213

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 1053

Subject Initials: (b) (6)

Is Blank

### Supine 12-Lead Electrocardiogram Report

Was ECG performed?	Date DD/MMM/YYYY	Actual Time 24-hour clock
<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	15-NOV-2010	08:03

Parameter	Unit	Result
Ventricular Heart Rate	beats/minute	58
PR Interval	milliseconds	166
QRS Duration	milliseconds	90
QT Interval	milliseconds	412
QTc Interval	milliseconds	404

ECG Interpretation:

☐ Normal ☒ Abnormal, NCS ☐ Abnormal, CS

Comments Regarding CS Findings:

### Oral Health Examination

Was Oral Health Examination performed? ☒ Yes ☐ No

Date  
DD/MMM/YYYY

15-NOV-2010

Exam Determination

Result

If Yes, Please Describe

Evidence of Leukoplakia?

☐ Yes ☒ No

Evidence of Other Oral Keratosis?

☐ Yes ☒ No

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_82 (v1, 15-OCT-2010)

Document Number R341633313

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DISCHARGE, DAY 6

Subject Number: 1053

Subject Initials: (b) (6)

Is Blank

Seated Vital Signs and HDYF? Inquiry

Were vital signs collected? ☒ Yes ☐ No

Date  
DD/MMM/YYYY

16-NOV-2010

Actual Time  
24-hour clock

07:03

Was HDYF?  
question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

132

Diastolic Blood Pressure

mmHg

91

Pulse

beats/minute

62

Respiratory Rate

breaths/minute

16

Oral Temperature

°C

36.4

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_83 (v1, 15-OCT-2010)

Document Number R341522313

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

#### Previous and Concomitant Medications

Has the subject taken any medications prior to the first dose and/or during the study as restricted by the protocol?

☐ Yes, list below. ☒ No

Drug Name:

Indication:

Dose:

Unit: Select only one

☐ grams

☐ micrograms

☐ milligrams

☐ milliliter

☐ tablet

☐ other, specify:

Frequency: Select only one

☐ one time

☐ whenever necessary

☐ every morning

☐ at bedtime

☐ every day

☐ twice daily

☐ three times daily

☐ four times daily

☐ every four hours

☐ every other day

☐ every week

☐ other, specify:

Route: Select only one

☐ Oral

☐ Topical

☐ Subcutaneous

☐ Intravenous

☐ Intramuscular

☐ Intradermal

☐ Ocular, Left

☐ Ocular, Right

☐ Ocular, Both

☐ Sublingual

☐ Other, specify:

Start Date

DD/MMM/YYYY

Stop Date

DD/MMM/YYYY

☐ Ongoing

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_84 (v1, 15-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

AE

Subject Number:

1053

Subject Initials:

(b) (6)

Is Blank

#### Adverse Events

Did the subject experience any adverse events? ☐ Yes, list below. ☒ No

Event Number:

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time

DD/MMM/YYYY

24-hour clock

DD/MMM/YYYY

24-hour clock

☐ Ongoing

Severity: Select only one

☐ Mild

☐ Moderate

☐ Severe

Action Taken Select only one

with Study ☐ Dose increased

☐ Treatment interrupted

Treatment: ☐ Dose not changed

☐ Treatment withdrawn

☐ Dose reduced

☐ Not applicable

Other Action Select all that apply

Taken with ☐ None

Subject: ☐ Required concomitant medication

☐ Required withdrawal from study

☐ Other, Specify:

Relationship Select only one

to Study Treatment: ☐ Not Related

☐ Possible

☐ Probable

☐ Definite

Serious Event: Select only one

☐ Yes

☐ No

Outcome: Select only one

☐ Recovered/Resolved

☐ Recovered/Resolved with Sequelae

☐ Recovering/Resolving

☐ Fatal

☐ Not Recovered/Not Resolved

☐ Unknown

Verified

☒ Approved

☒ Locked

☒ Frozen

☒

Page Version No. PAGE\_85 (v1, 19-OCT-2010)

Document Number

R341524713

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name VS ADDITIONAL

Subject Number: 1053

Subject Initials: (b) (6)

Is Blank

### Additional Assessments - Vital Signs

Were any additional vital signs collected? ☒ Yes, list below. ☐ No

Date DD/MMM/YYYY 13-NOV-2010  
Actual Time 24-hour clock 08:12  
Position

☐ Standing

☐ Supine

☒ Seated

☐ Other, Specify:

Parameter	Unit	Result
Systolic Blood Pressure	mmHg	140
Diastolic Blood Pressure	mmHg	94
Pulse	beats/minute	ND
Respiratory Rate	breaths/minute	ND
Oral Temperature	°C	ND

Date DD/MMM/YYYY 16-NOV-2010  
Actual Time 24-hour clock 07:06  
Position

☐ Standing

☐ Supine

☒ Seated

☐ Other, Specify:

Parameter	Unit	Result
Systolic Blood Pressure	mmHg	138
Diastolic Blood Pressure	mmHg	90
Pulse	beats/minute	ND
Respiratory Rate	breaths/minute	ND
Oral Temperature	°C	ND

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_86 (v1, 18-OCT-2010)

Document Number R340146413



## **Links to Discrepancy and Audit Sections**

[Click here to navigate to audit history for this CRF](#)

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name VS ADDITIONAL

Subject Number: 1053

Subject Initials: (b) (6)

Is Blank

### Additional Assessments - Vital Signs

Were any additional vital signs collected? ☒ Yes, list below. ☐ No

Date DD/MMM/YYYY 28-OCT-2010  
Actual Time 24-hour clock 13:10  
Position  
☐ Standing  
☐ Supine  
☒ Seated  
☐ Other, Specify:

Parameter	Unit	Result
Systolic Blood Pressure	mmHg	138
Diastolic Blood Pressure	mmHg	90
Pulse	beats/minute	ND
Respiratory Rate	breaths/minute	ND
Oral Temperature	°C	ND

Date DD/MMM/YYYY  
Actual Time 24-hour clock  
Position  
☐ Standing  
☐ Supine  
☐ Seated  
☐ Other, Specify:

Parameter	Unit	Result
Systolic Blood Pressure	mmHg	
Diastolic Blood Pressure	mmHg	
Pulse	beats/minute	
Respiratory Rate	breaths/minute	
Oral Temperature	°C	

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_86 (v1, 18-OCT-2010)

Document Number R341634413

## **Links to Discrepancy and Audit Sections**

[Click here to navigate to audit history for this CRF](#)

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name LB ADDITIONAL

Subject Number: 1053

Subject Initials: (b) (6)

Is Blank

Additional Assessments - Laboratory Evaluations

Were any additional laboratory evaluations collected? ☐ Yes, list below. ☒ No

Date	Requisition	Clinically	Test Name	Test Code ID	
DD/MMM/YYYY	Number	Significant?	CS Labs Only	CS Labs Only	Comments
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_87 (v1, 15-OCT-2010)

Document Number R341779413

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name EG ADDITIONAL

Subject Number: 1053

Subject Initials: (b) (6)

Is Blank

Additional Assessments - 12-Lead Electrocardiogram Report

Were any additional 12-lead ECGs collected? ☒ Yes, list below. ☐ No

Date DD/MMM/YYYY Actual Time 24-hour clock  
15-NOV-2010 08:42

Parameter	Unit	Result
Ventricular Heart Rate	beats/minute	53
PR Interval	milliseconds	168
QRS Duration	milliseconds	88
QT Interval	milliseconds	416
QTc Interval	milliseconds	390

ECG Interpretation:

☐ Normal ☒ Abnormal, NCS ☐ Abnormal, CS

Comments Regarding CS Findings:

Date DD/MMM/YYYY Actual Time 24-hour clock

Parameter	Unit	Result
Ventricular Heart Rate	beats/minute	<input type="text"/>
PR Interval	milliseconds	<input type="text"/>
QRS Duration	milliseconds	<input type="text"/>
QT Interval	milliseconds	<input type="text"/>
QTc Interval	milliseconds	<input type="text"/>

ECG Interpretation:

☐ Normal ☐ Abnormal, NCS ☐ Abnormal, CS

Comments Regarding CS Findings:

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_88 (v1, 15-OCT-2010)

Document Number R341634613

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name **STUDY COMPLETION**

Subject Number: **1053**

Subject Initials: **(b) (6)**

Is Blank

### Study Completion

Date the subject completed OR withdrew from the study: **16-NOV-2010**  
DD/MMM/YYYY

Reason for Withdrawal (check one):

☒ NA, Completed Study

☐ Adverse Event, specify:

☐ Terminated by Sponsor

☐ Consent Withdrawn

☐ Lost to Follow-up

☐ Other, specify:

Investigator Comments (if none, leave blank):

By electronically approving this case report form, I have reviewed the data  
and found them to be complete and accurate.

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. **PAGE\_89 (v1, 15-OCT-2010)**

Document Number **R341634813**

## Appendix: Audit and Discrepancy Information





# Audit History Report

This section lists audited data that meets the parameters set when the report was run. It may not include all of the audited data in a particular CRF. Refer to the documentation for a complete description of the parameters that can affect this report.

**Document #:** R340144013

<b>Patient</b>	<b>Visit</b>	<b>CRF</b>
<b>Site</b>	<b>Visit Date</b>	<b>CRF Page</b>
1053	Screen 1	Page_10
M01		010

<b>Section</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
<b>Section Date</b>			

<b>Group #</b>	<b>Group Name</b>
0	CRF Header

<b>Field</b>	<b>Changed From</b>	<b>Impact on</b>	<b>On</b>	<b>Reason</b>
<b>Row</b>	<b>Changed To</b>	<b>resequence</b>	<b>By</b>	<b>Comment</b>
DCI Blank Flag	N		20-NOV-2010 16:35:19	Data Entry Error
1	Y		Matthew Mickelson	
DCI Blank Flag	Y		20-NOV-2010 16:35:46	Data Entry Error
1	N		Matthew Mickelson	

**Document #:** R340144013

<b>Patient</b>	<b>Visit</b>	<b>CRF</b>
<b>Site</b>	<b>Visit Date</b>	<b>CRF Page</b>
1053	Screen 1	Page_10
M01		010

<b>Section</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
<b>Section Date</b>			
Drugscr	Page number	10	Screen 1

<b>Group #</b>	<b>Group Name</b>
1	DRUG

<b>Field</b>	<b>Changed From</b>	<b>Impact on</b>	<b>On</b>	<b>Reason</b>
<b>Row</b>	<b>Changed To</b>	<b>resequence</b>	<b>By</b>	<b>Comment</b>
Date			20-NOV-2010 16:35:46	Row Inserted
1	22-OCT-2010		Matthew Mickelson	
Urine Drug			20-NOV-2010 16:35:46	Row Inserted
Screen Result	NEGATIVE		Matthew Mickelson	
1				
Was Urine Drug			20-NOV-2010 16:35:46	Row Inserted
Screen	YES		Matthew Mickelson	
Performed?				
1				

**Document #:** R340144013

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
1053	Screen 1	Page_10
M01		010

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Preg	Page number	10	Screen 1

<b>Group #</b>	<b>Group Name</b>
1	ALC

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Was Urine Pregnancy Test Performed? 1	NA MALE	20-NOV-2010 16:35:46 Matthew Mickelson	Row Inserted

**Document #:** R340144513

<b>Patient</b>	<b>Visit</b>	<b>CRF</b>
<b>Site</b>	<b>Visit Date</b>	<b>CRF Page</b>
1053	Screen 2	Page_13
M01		013

<b>Section</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
<b>Section Date</b>			
Pe	Page number	13	Screen 2

<b>Group #</b>	<b>Group Name</b>
2	VIS

<b>Field</b>	<b>Changed From</b>	<b>Impact on</b>	<b>On</b>	<b>Reason</b>
<b>Row</b>	<b>Changed To</b>	<b>resequence</b>	<b>By</b>	<b>Comment</b>
Date	22-OCT-2010		20-NOV-2010 16:37:13	Data Entry Error
1	28-OCT-2010		Matthew Mickelson	

**Document #:** R340144813

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
1053	Screen 2	Page_14
M01		014

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Usual	Page number	14	Screen 2

<b>Group #</b>	<b>Group Name</b>
1	INDYN

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Usual Brand Name Result (1) 1	MARBORO GOLD PACK MARLBORO GOLD PACK	29-MAR-2011 10:36:29 Dawn Winter	Data Entry Error

**Document #:** R341499913

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>	
1053	Check-In, Day -2	Page_17	
M01		017	
<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Vs	Page number	17	Check-In, Day -2
<b>Group #</b>	<b>Group Name</b>		
1	VS		
<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Was HDYF? question asked? (2) 1	YES NO	21-FEB-2011 09:30:54 Dawn Winter	Data Entry Error

**Document #:** R341503213

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>	
1053	Baseline, Day -1	Page_20	
M01		020	
<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Pcu	Page number	20	Baseline, Day -1
<b>Group #</b>	<b>Group Name</b>		
1	PCU		
<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Start Time	0708	21-FEB-2011 09:34:27	Data Entry Error
1	0648	Dawn Winter	



**Document #:** R341521813

<b>Patient</b>	<b>Visit</b>	<b>CRF</b>
<b>Site</b>	<b>Visit Date</b>	<b>CRF Page</b>
1053	Day 1	Page_23
M01		023

<b>Section</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
<b>Section Date</b>			
Alc	Page number	23	Day 1

<b>Group #</b>	<b>Group Name</b>
1	SU

<b>Field</b>	<b>Changed From</b>	<b>Impact on</b>	<b>On</b>	<b>Reason</b>
<b>Row</b>	<b>Changed To</b>	<b>resequence</b>	<b>By</b>	<b>Comment</b>
12-ounce serving of Ultralight Beer (1) 1	2 02		23-DEC-2010 11:00:22 Luis Hernandez	Data Entry Error
6-ounce serving of White or Rose Wine (2) 1	00		23-DEC-2010 11:00:22 Luis Hernandez	Data Entry Error

**Document #:** R341521913

<b>Patient</b>	<b>Visit</b>	<b>CRF</b>	
<b>Site</b>	<b>Visit Date</b>	<b>CRF Page</b>	
1053	Day 2	Page_35	
M01		035	
<b>Section</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
<b>Section Date</b>			
Alc	Page number	35	Day 2

<b>Group #</b>	<b>Group Name</b>
1	SU

<b>Field</b>	<b>Changed From</b>	<b>Impact on</b>	<b>On</b>	<b>Reason</b>
<b>Row</b>	<b>Changed To</b>	<b>resequence</b>	<b>By</b>	<b>Comment</b>
12-ounce serving of Ultralight Beer (1) 1	2 02		23-DEC-2010 10:59:53 Luis Hernandez	Data Entry Error
6-ounce serving of White or Rose Wine (2) 1	00		23-DEC-2010 10:59:53 Luis Hernandez	Data Entry Error

Document #: R341522013

Patient	Visit	CRF	
Site	Visit Date	CRF Page	
1053	Day 3	Page_45	
M01		045	
Section	Qualifying Prompt	Qualifying Value	Section Visit
Section Date			
Alc	Page number	45	Day 3

Group #	Group Name
1	SU

Field	Changed From	Impact on	On	Reason
Row	Changed To	resequence	By	Comment
12-ounce serving of Ultralight Beer (1) 1	2 02		23-DEC-2010 10:59:11 Luis Hernandez	Data Entry Error
6-ounce serving of White or Rose Wine (2) 1	00		23-DEC-2010 10:59:11 Luis Hernandez	Data Entry Error

**Document #:** R341624513

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>	
1053	Day 3	Page_54	
M01		054	
<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Ub_Disp	Page number	54	Day 3

<b>Group #</b>	<b>Group Name</b>
1	SU

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
If No, Comment 1		01-DEC-2010 14:23:38 Luis Hernandez	Row Inserted
If No, Comment 2		01-DEC-2010 14:23:38 Luis Hernandez	Row Inserted
If No, Comment 3		01-DEC-2010 14:23:38 Luis Hernandez	Row Inserted
If No, Comment 4		01-DEC-2010 14:23:38 Luis Hernandez	Row Inserted
If No, Comment 5		01-DEC-2010 14:23:38 Luis Hernandez	Row Inserted
If No, Comment 6		01-DEC-2010 14:23:38 Luis Hernandez	Row Inserted
Cigarette Butt Length (mm) 7		01-DEC-2010 14:23:38 Luis Hernandez	Row Inserted
Date 7		01-DEC-2010 14:23:38 Luis Hernandez	Row Inserted
If No, Comment 7		01-DEC-2010 14:23:38 Luis Hernandez	Row Inserted
Seq 7		01-DEC-2010 14:23:38 Luis Hernandez	Row Inserted
Time UB Dispensed (1) 7		01-DEC-2010 14:23:38 Luis Hernandez	Row Inserted
Time UB Returned (2) 7		01-DEC-2010 14:23:38 Luis Hernandez	Row Inserted

Document #: R341625913

Patient	Visit	CRF
Site	Visit Date	CRF Page
1053	Day 3	Page_55
M01		055

Section	Qualifying Prompt	Qualifying Value	Section Visit
Section Date			
Pcu	Page number	55	Day 3

Group #	Group Name
1	PCU

Field	Changed From	Impact on	On	Reason
Row	Changed To	resequence	By	Comment
Start Time	0708		21-FEB-2011 09:35:25	Data Entry Error
1	0648		Dawn Winter	

**Document #:** R341522113

<b>Patient</b>	<b>Visit</b>	<b>CRF</b>	
<b>Site</b>	<b>Visit Date</b>	<b>CRF Page</b>	
1053	Day 4	Page_57	
M01		057	
<b>Section</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
<b>Section Date</b>			
Alc	Page number	57	Day 4

<b>Group #</b>	<b>Group Name</b>
1	SU

<b>Field</b>	<b>Changed From</b>	<b>Impact on</b>	<b>On</b>	<b>Reason</b>
<b>Row</b>	<b>Changed To</b>	<b>resequence</b>	<b>By</b>	<b>Comment</b>
12-ounce serving of Ultralight Beer (1) 1	2 02		23-DEC-2010 10:58:33 Luis Hernandez	Data Entry Error
6-ounce serving of White or Rose Wine (2) 1	00		23-DEC-2010 10:58:33 Luis Hernandez	Data Entry Error

**Document #:** R341522213

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>	
1053 M01	Day 5/Early Term	Page_67 067	
<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Alc	Page number	67	Day 5/Early Term

  

<b>Group #</b>	<b>Group Name</b>		
1	SU		

  

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
12-ounce serving of Ultralight Beer (1) 1	2 02	23-DEC-2010 10:49:18 Luis Hernandez	Data Entry Error
6-ounce serving of White or Rose Wine (2) 1	00	23-DEC-2010 10:49:18 Luis Hernandez	Data Entry Error

**Document #:** R341631613

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>	
1053	Day 5/Early Term	Page_77	
M01		077	
<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Pcu	Page number	77	Day 5/Early Term
<b>Group #</b>	<b>Group Name</b>		
1	PCU		
<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Start Time	0708	21-FEB-2011 09:36:45	Data Entry Error
1	0648	Dawn Winter	



**Document #:** R341632713

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>	
1053	Day 5/Early Term	Page_80	
M01		080	
<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Lb	Page number	80	Day 5/Early Term
<b>Group #</b>	<b>Group Name</b>		
1	LB		
<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Requisition Number 2 (if applicable): (2)	G799639	17-FEB-2011 07:59:19 Dawn Winter	Data Entry Error
1			

Document #: R340146413

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>	
1053	Vs Additional	Page_86	
M01		086	
<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Vs	Page number	86	Vs Additional

<b>Group #</b>	<b>Group Name</b>
1	VS

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Actual Time/Actual Time Vitals Collected (1) 1	1310 0812	30-NOV-2010 18:25:58 Ashley Jeffrey	Pass1
Date 1	28-OCT-2010 13-NOV-2010	30-NOV-2010 18:25:58 Ashley Jeffrey	Pass1
Diastolic Blood Pressure (mmHg) 1	90 94	30-NOV-2010 18:25:58 Ashley Jeffrey	Pass1
Oral Temperature (C) 1	ND NA	30-NOV-2010 18:25:58 Ashley Jeffrey	Pass1
Oral Temperature (C) 1	NA ND	21-FEB-2011 10:12:16 Luis Hernandez	Data Entry Error
Pulse (beats/minute) 1	ND NA	30-NOV-2010 18:25:58 Ashley Jeffrey	Pass1
Pulse (beats/minute) 1	NA ND	21-FEB-2011 10:12:16 Luis Hernandez	Data Entry Error
Respiratory Rate (breaths/minute) (1) 1	ND NA	30-NOV-2010 18:25:58 Ashley Jeffrey	Pass1
Respiratory Rate (breaths/minute) (1) 1	NA ND	21-FEB-2011 10:12:16 Luis Hernandez	Data Entry Error
Systolic Blood Pressure (mmHg) 1	138 140	30-NOV-2010 18:25:58 Ashley Jeffrey	Pass1
Actual Time/Actual Time Vitals Collected (1) 2	0654 0706	01-DEC-2010 14:49:52 Luis Hernandez	Data Entry Error

**Document #:** R340146413

<b>Patient</b>	<b>Visit</b>	<b>CRF</b>	
<b>Site</b>	<b>Visit Date</b>	<b>CRF Page</b>	
1053	Vs Additional	Page_86	
M01		086	
<b>Section</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
<b>Section Date</b>			
Vs	Page number	86	Vs Additional

<b>Group #</b>	<b>Group Name</b>
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1	VS
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Oral Temperature	NA	21-FEB-2011 10:12:16	Data Entry Error
(C)	ND	Luis Hernandez	
2			

Pulse	NA	21-FEB-2011 10:12:16	Data Entry Error
(beats/minute)	ND	Luis Hernandez	
2			

Respiratory Rate	NA	21-FEB-2011 10:12:16	Data Entry Error
(breaths/minute)	ND	Luis Hernandez	
(1)			
2			

**Document #:** R341634413

<b>Patient</b>	<b>Visit</b>	<b>CRF</b>
<b>Site</b>	<b>Visit Date</b>	<b>CRF Page</b>
1053	Vs Additional.1	Page_86
M01		

<b>Section</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
<b>Section Date</b>			
Vs	Page number	86	Vs Additional.1

<b>Group #</b>	<b>Group Name</b>
1	VS

<b>Field</b>	<b>Changed From</b>	<b>Impact on</b>	<b>On</b>	<b>Reason</b>
<b>Row</b>	<b>Changed To</b>	<b>resequence</b>	<b>By</b>	<b>Comment</b>
Oral Temperature (C) 1	NA ND		21-FEB-2011 10:13:06 Luis Hernandez	Data Entry Error
Pulse (beats/minute) 1	NA ND		21-FEB-2011 10:13:06 Luis Hernandez	Data Entry Error
Respiratory Rate (breaths/minute) (1) 1	NA ND		21-FEB-2011 10:13:06 Luis Hernandez	Data Entry Error

# Discrepancy Detail Report

Document #: R340142613

Discrepancy ID: 261976811

Site: M01

Patient: 1053

Visit: SCREEN 1

Visit Date:

CRF: PAGE\_02

Section: IC

Qualifying Value: 2

Field:

Row:

Value Text:

Type: MULTIVARIATE

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Inclusion Criterion #5 is Yes, but Expired-Air CO (ECO) level is less than 15 ppm at Screening. Please verify inclusion criterion response and Expired-Air CO (ECO) level response and update as appropriate.

Internal Comment: was repeated

Resolution Type: Confirmed

Resolution Text:

**Document #: R340143713**

**Discrepancy ID:** 247206811

**Site:** M01

**Patient:** 1053

**Visit:** SCREEN 1

**Visit Date:**

**CRF:** PAGE\_08

**Section:** BM

**Qualifying Value:** 8

**Field:**

**Row:**

**Value Text:**

**Type:** MULTIVARIATE

**Status:** CURRENT

**Review Status:** Resolved-Response Edited

**Discrepancy:** Subject's BMI 31.5 is less than 18.0 or greater than 30.0 kg/m2. Please reconcile.

**Internal Comment:**

**Resolution Type:** Confirmed

**Resolution Text:**

**Document #: R340144513**

**Discrepancy ID:** 299359811                      **Site:** M01                      **Patient:** 1053  
**Visit:** SCREEN 2                      **Visit Date:**  
**CRF:** PAGE\_13                      **Section:** PE                      **Qualifying Value:** 13  
**Field:** Does the subject have any relevant findi                      **Row:** 1  
**Value Text:** NO  
**Type:** MANUAL                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Please clarify if tremor considered relevant to study.  
**Internal Comment:** Docs marked it as ncs  
**Resolution Type:** Confirmed  
**Resolution Text:**

**Document #: R340144813**

**Discrepancy ID:** 308401211                      **Site:** M01                      **Patient:** 1053  
**Visit:** SCREEN 2                      **Visit Date:**  
**CRF:** PAGE\_14                      **Section:** USUAL                      **Qualifying Value:** 14  
**Field:** Usual Brand Name Result                      **Row:** 1  
**Value Text:** MARLBORO GOLD PACK  
**Type:** MANUAL                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Please verify the Usual Brand Name, as this is not recognizable.  
**Internal Comment:** spelling corrected  
**Resolution Type:** Data value changed. Disc no longer applicable.  
**Resolution Text:**



**Document #: R340145413**

<b>Discrepancy ID:</b> 247207411	<b>Site:</b> M01	<b>Patient:</b> 1053
<b>Visit:</b> SCREEN 2	<b>Visit Date:</b>	
<b>CRF:</b> PAGE_15	<b>Section:</b> VS	<b>Qualifying Value:</b> 15
<b>Field:</b> ECO (ppm)		<b>Row:</b> 1
<b>Value Text:</b> 14		
<b>Type:</b> MANUAL	<b>Status:</b> CURRENT	
<b>Review Status:</b> Resolved-Response Edited		
<b>Discrepancy:</b>		
<b>Internal Comment:</b> on 03nov2010, ECO was 19		
<b>Resolution Type:</b> Confirmed		
<b>Resolution Text:</b>		

**Document #: R341499913**

**Discrepancy ID:** 299678111                      **Site:** M01                      **Patient:** 1053  
**Visit:** CHECK-IN, DAY -2   **Visit Date:**  
**CRF:** PAGE\_17                      **Section:** VS                      **Qualifying Value:** 17  
**Field:** Was HDYF? question asked?                      **Row:** 1  
**Value Text:** NO  
**Type:** MANUAL                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Please update per source. It appears HDYF was not asked.  
**Internal Comment:**  
**Resolution Type:** Confirmed  
**Resolution Text:**

**Document #: R341503213**

**Discrepancy ID:** 299682411                      **Site:** M01                      **Patient:** 1053  
**Visit:** BASELINE, DAY -1   **Visit Date:**  
**CRF:** PAGE\_20                      **Section:** PCU                      **Qualifying Value:** 20  
**Field:** Start Time                      **Row:** 1  
**Value Text:** 0648  
**Type:** MANUAL                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Please clarify nominal urine collection start time (07:08 vs 06:48).  
**Internal Comment:**  
**Resolution Type:** Confirmed  
**Resolution Text:**

**Document #: R341624513**

**Discrepancy ID:** 259897411                      **Site:** M01                      **Patient:** 1053  
**Visit:** DAY 3                      **Visit Date:**  
**CRF:** PAGE\_54                      **Section:** UB\_DISP                      **Qualifying Value:** 54  
**Field:** Mouth-End Filter Cut for YIU?                      **Row:** 7  
**Value Text:**  
**Type:** UNIVARIATE                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Value for Mouth-End Filter Cut for YIU? has not been supplied  
**Internal Comment:**  
**Resolution Type:** Confirmed  
**Resolution Text:**

**Document #: R341625913**

**Discrepancy ID:** 299690811                      **Site:** M01                      **Patient:** 1053  
**Visit:** DAY 3                      **Visit Date:**  
**CRF:** PAGE\_55                      **Section:** PCU                      **Qualifying Value:** 55  
**Field:** Start Time                      **Row:** 1  
**Value Text:** 0648  
**Type:** MANUAL                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Please clarify nominal urine collection start time (07:08 vs 06:48).  
**Internal Comment:**  
**Resolution Type:** Confirmed  
**Resolution Text:**

**Document #: R341631613**

**Discrepancy ID:** 299691211                      **Site:** M01                      **Patient:** 1053  
    **Visit:** DAY 5/EARLY TER    **Visit Date:**  
    **CRF:** PAGE\_77                      **Section:** PCU                      **Qualifying Value:** 77  
    **Field:** Start Time                      **Row:** 1  
    **Value Text:** 0648  
    **Type:** MANUAL                      **Status:** CURRENT  
    **Review Status:** Resolved-Response Edited  
    **Discrepancy:** Please clarify nominal urine collection start time (07:08 vs 06:48).  
**Internal Comment:**  
    **Resolution Type:** Confirmed  
    **Resolution Text:**

# Deleted CRFs Report