

CRF Report for Study E6270229

Report run by Jaedeanne Shaver at 11-01-2008 10:34:41

Report Parameters

Site: CD_001

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: 2002

Ending patient: 2002

Legend: How different values appear in the report

Prompt	Abc 123
Data value	Abc 123
Data value with discrepancy	Abc 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)

Data Clarification Form

To: Covance CRU Dallas
Investigator: Patricia Chandler
Date: 01-MAR-2008

Patient#: 2002
Patient Initials:
Reviewer: Dawn Taylor

Form Name / Visit Name	Page # Date	Questions/Comments	Resolution
Laboratory Evaluation WEEK 0 (BASELINE) Disc ID: 1334976513 Type: MANUAL	5 06MAR07 Closed: N	1-Please verify the date associated with lab req #N526967. 2-Urine collection lab req (#N528056) was not provided with this crf. 3-07Mar07 UA Lab document notes a requested repeat. Please verify if the repeat was conducted.	1- <input checked="" type="checkbox"/> 07-03-2007 [] Other: _____ 2- <input checked="" type="checkbox"/> Req attached [] Other: _____ 3- <input checked="" type="checkbox"/> Repeat ND SEE NTF [] Repeat done Req # _____ attached Date: _____ CS? _____
Medical History SCREENING Disc ID: 1334976413 Type: MANUAL	3 07FEB07 Closed: N	As finding Pneumonia resolved well before study entry, please verify if it should be deleted.	<input checked="" type="checkbox"/> Delete [] Maintain

I have completed, reviewed and either approved all the corrections on this form or made some corrections and initialled those changes. I verify that I have received a copy of this form which will be filed with my copy of the appropriate Case Report Form.

Authorized Personnel Signature

Date

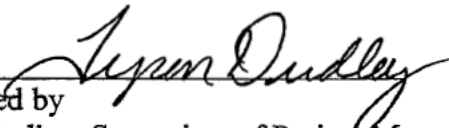
NOTE TO STUDY FILE

Study No: 207268
Protocol No: 6270-229


Group: 1
Subject: R2002-(b) (6) /
Study Week: Week 0 (07MAR2007)

A repeat Micro/Macro Urinalysis was requested by the investigator, but was inadvertently not performed.

COPY


Generated by
Tyson Dudley, Supervisor of Project Management

10 Jan 2008
Date


Authorized by
Patricia Chandler, Principal Investigator

10 Jan 2008
Date

Covance CLS

Marietta Henry, M.D., Director
8211 SciCor Drive - Indianapolis, IN 46214-2985
Tel. +1 (800) 327 7270

LABORATORY REPORT

ACCESSION NO. N528056

Page 1 of 1

INVESTIGATOR: (B17175)

Patricia Chandler, M.D.
c/o Tepan Mehta
Radiant Research Inc
1341 W Mockingbird Ln/Ste 400E
Dallas, TX 75247

SPONSOR REPORT TO:

Russell M. Dixon, MD
Medical Director
Covance CRU, Inc.
3402 Kinsman Boulevard
Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 24 HR UR

24 Hr Urine Collection

COLLECTION TIME: 16:56 DATE: 06-Mar-2007

DATE RECEIVED IN LABORATORY: 09-Mar-2007

DATE REPORTED BY LABORATORY: 09-Mar-2007

SEX: F BIRTHDATE: (b) (6) AGE: 40

SCREENING NUMBER: S2006

Is this Clinically
Significant/ Adverse
Event?

Yes

No

URINE CREATININE, 24 HR

U24h Creat 1306

600-1600 mg/24hr

UAlq24Crea 91.2

mg/dL No Ref Rng

ELAPSED DATE AND TIME, 24HR

Elpsd D&T 1307

min

24 HR COLLECTION INFORMATION

Start Date 06-Mar-2007

Start Time 16:56

Stop Date 07-Mar-2007


Stop Time ~~14:43~~ 1442 AW 05mar2008

TOTAL 24HR URINE VOLUME

Total Vol. 1300

mL

QC'D

~~28 MAR 2007~~
Investigator Signature:
Date:

H(High) or L(Low)=Values above or below Covance CLS reference range
T=Telephoned P="Panic" EX=Exclusion-as specified by the sponsor

B17175

(INV)

Page ID: D11580413

/ Covance No. 6270-229

Data Clarification Form

To: Covance CRU Dallas
Investigator: Patricia Chandler
Date: 01-MAR-2008

Patient#: 2002
Patient Initials:
Reviewer: Dawn Taylor

Form Name / Visit Name	Page # Date	Questions/Comments	Resolution
Unused Study Product Returned WEEK 1 Disc ID: 1334976713 Type: MANUAL	8 13MAR07 Closed: N	Amount Returned 'Packs' was not completed for the following W1 flavors:	Original: <u>0</u> Frost: <u>0</u> Spice: <u>0</u>

Am2
03/2008

I have completed, reviewed and either approved all the corrections on this form or made some corrections and initialled those changes. I verify that I have received a copy of this form which will be filed with my copy of the appropriate Case Report Form.

Authorized Personnel Signature

Date

Data Clarification Form

To: Covance CRU Dallas
Investigator: Patricia Chandler
Date: 01-MAR-2008

Patient#: 2002
Patient Initials:
Reviewer: Dawn Taylor

Form Name / Visit Name	Page # Date	Questions/Comments	Resolution
Study Product Dispensation WEEK 0 (BASELINE) Disc ID: 1334976613 Type: MANUAL	5.2 07MAR07 Closed: N	Amount dispensed for Frost and Spice flavors currently presented is 62 & 60, respectively. The value to be reported here is the number of packets. Number provided appears to be pouches. Please verify amount dispensed for these flavors.	<input checked="" type="checkbox"/> Frost=1 Spice=1 <input type="checkbox"/> Frost=_____ Spice=_____
Study Product Dispensation WEEK 1 Disc ID: 1334976813 Type: MANUAL	8 13MAR07 Closed: N	As no study product was dispensed at the W1 visit, please confirm this data module should be marked BLANK? Y.	<input checked="" type="checkbox"/> Module=BLANK? Y <input type="checkbox"/> Other:_____

I have completed, reviewed and either approved all the corrections on this form or made some corrections and initialled those changes. I verify that I have received a copy of this form which will be filed with my copy of the appropriate Case Report Form.

Authorized Personnel Signature

06 Mar 2008
Date

CRF Report for Study E6270229



Patient: 2002
CRF: Header_Page
Visit: SCREENING
Entered By: Sharon Ladenes
Discrepancies: None
Approval Status: Not Approved
Verification: Not Verified
Comment:

Site: CD_001
Blank? N
Visit Date: 07-02-2007
Entry Time: 16-05-2007 11:54:02
Modification Time: 12-07-2007 17:33:06
Approval Time:
Verification Time:

Investigator: RR_001
CRF Page #: 1
Document #: R142050513
CRF Status: Entry Complete

Approver:
Verifier:

Section: Header_Info	Blank? N	Section Status: Entry Complete
Visit: SCREENING	Section Date: 07-02-2007	
Entered By: Sharon Ladenes	Entry Time: 16-05-2007 11:54:02	
	Last Modification Time: 12-07-2007 17:33:06	
	Page number: 1	

RDC CASE REPORT FORM		SMOKER
Sponsor Name	Investigator	Site
RJ REYNOLDS TOBACCO COMPANY	PATRICIA A. CHANDLER, MD	DALLAS 002
SWITCHING FROM USUAL BRAND CIGARETTES TO A TOBACCO-HEATING CIGARETTE OR SNUS		
-A MULTI-CENTER EVALUATION OF HEALTH-RELATED QUALITY OF LIFE ASSESSMENTS AND BIOMARKERS		
OF EXPOSURE AND HARM		

CRF Report for Study E6270229

Patient: 2002
 CRF: Screening
 Visit: SCREENING
 Entered By: Sharon Ladenes
 Discrepancies: None
 Approval Status: Not Approved
 Verification: Not Verified
 Comment:

Site: CD_001
 Blank? N
 Visit Date: 07-02-2007
 Entry Time: 22-05-2007 12:01:46
 Modification Time: 22-05-2007 12:09:10
 Approval Time:
 Verification Time:

Investigator: RR_001
 CRF Page #: 2
 Document #: R142585313
 CRF Status: Entry Complete
 Approver:
 Verifier:

Section: Inc_Criteria	1 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 07-02-2007	
Entered By: Sharon Ladenes		Entry Time: 22-05-2007 12:01:46	
		Last Modification Time: 22-05-2007 12:09:10	
		Page number: 2	

INCLUSION CRITERIA		
Sequence number		Yes/No
01	Males of females, between 31 and 55 years of age, inclusive.	YES
02	Subjects in Groups A, B, and C, must be cigarette-only smokers who currently smoke at least 15 cigarettes daily and who have smoked for at least 10 years prior to Week 0 (i.e., chronic cigarette smokers).	YES
03	Smokers of ultralight, regular, and menthol cigarettes will be eligible.	YES
04	Not intending to quit smoking, but willing to switch their tobacco product (intent to quit is defined as intending to make or making a quit attempt within 1 month prior to Week 0).	YES
05	Subjects for Group D must be self-reported never smokers per the ATS definition (see The American Thoracic Society Questionnaire).	NA, GROUP
06	Subjects must, in the opinion of the Investigators, be free of clinically significant health problems.	YES
07	Not be on medication on a daily basis for chronic medical disorders deemed clinically significant by the Investigator.	YES
08	Not be regularly taking creatine supplements.	YES
09	Negative test for selected drugs of abuse at Screening (includes alcohol test).	YES
10	Negative hepatitis panel (including HBsAg and anti-HCV) and negative HIV antibody screens (for subjects who have been immunized against hepatitis B and have documentation of this immunization, a positive result for HBsAg is not exclusionary).	YES

Section: Inc_Criteria	2 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 07-02-2007	
Entered By: Sharon Ladenes		Entry Time: 22-05-2007 12:01:46	
		Last Modification Time: 22-05-2007 12:09:10	
		Page number: 20	

INCLUSION CRITERIA		
Sequence number		Yes/No
	Females will be non-pregnant (for all females, the pregnancy test results must be negative)	

CRF Report for Study E6270229

Patient: 2002

CRF: Screening

Visit: SCREENING

Site: CD_001

Blank? N

Visit Date: 07-02-2007

Investigator: RR_001

CRF Page #: 2

Document #: R142585313

Section: Inc_Criteria		2 of 10
11	at Screening; and for all females of child-bearing potential, the pregnancy test results must be negative at Weeks 0, 12, and 24), non-lactating, and either postmenopausal (as verified by FSH levels) for at least 1 year, surgically sterile (e.g. 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 Week 24 (of Study Completion) a form of contraception considered acceptable to the Investigators (such as oral, injectable, or implantable contraceptives, intrauterine devices and barrier methods).	YES
12	Able to comprehend and willing to sign an Informed Consent Form (ICF).	YES
13	Able to read and comprehend questionnaires in English.	YES

Section: Exc_Criteria	3 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 07-02-2007	
Entered By: Sharon Ladenes		Entry Time: 22-05-2007 12:01:46	
		Last Modification Time: 22-05-2007 12:09:10	
		Page number: 3	

Exclusion Criteria		
Sequence number		Yes/No
01	For Groups A, B, and C, regular use of any other tobacco or nicotine-containing product or device other than tobacco burning cigarettes from 6 months prior to the study through Week 24, including cigars, pipes, chewing tobacco, snuff, snus, nicotine patch, nicotine gum, etc.	NO
02	History or clinical manifestations of significant metabolic, hepatic, renal, hematological, pulmonary, cardiovascular, gastrointestinal, urological, neurological, or psychiatric disorders.	NO
03	History of hypersensitivity or allergies to any drug compound unless approved by the Investigator(s).	NO
04	History or presence of an abnormal ECG, which, in the Investsigator(s)' opinion, is clinically significant.	NO
05	History of alcoholism or drug addiction within 1 year prior to Study Entry; excessive alcohol consumption will be discouraged.	NO
06	Poor peripheral venous access.	NO
07	Donation of blood from 30 days prior to Screening through Week 24 (or Study Completion), inclusive, or of plasma from 2 weeks prior to Screening through Week 24 (or Study Completion), inclusive.	NO
08	Receipt of blood products within 2 months prior to Study Entry.	NO
09	Evidence of visible oral cancer, as found in an oral health examination or based on oral health questions at each visit.	NO
10	Any acute or chronic condition that, in the Investigator(s)' opinion, would limit the subject's ability to complete and/or participate in this clinical study.	NO
11	Subject or a relative of the subject is or has ever been employed by the tobacco industry.	NO
12	Subject is an employee of Covance.	NO
13	Subject has participated in any other investigational study drug or product trial in which receipt of an investigational study drug or product ocured within 30 days prior to Check-in (inclusive).	NO

CRF Report for Study E6270229

Patient: 2002

CRF: Screening

Visit: SCREENING

Site: CD_001

Blank? N

Visit Date: 07-02-2007

Investigator: RR_001

CRF Page #: 2

Document #: R142585313

Section: Informed Consent	4 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 07-02-2007	
Entered By: Sharon Ladenes		Entry Time: 22-05-2007 12:01:46	
		Last Modification Time: 22-05-2007 12:09:10	
		Page number: 4	
Informed Consent			
Date the Subject Signed the Smoker Informed Consent Form		07-02-2007	

Section: Elig	5 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 07-02-2007	
Entered By: Sharon Ladenes		Entry Time: 22-05-2007 12:01:46	
		Last Modification Time: 22-05-2007 12:09:10	
		Page number: 4	
Subject Eligibility			
Did the subject meet all of the inclusion criteria?		YES	
Did the subject have any of the exclusion criteria?		NO	
Criteria	Criteria		
Type	Number	Deviation	Date Exemption Granted

Section: Patient_Rep_Outc	6 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 07-02-2007	
Entered By: Sharon Ladenes		Entry Time: 22-05-2007 12:01:46	
		Last Modification Time: 22-05-2007 12:09:10	
		Page number: 4	
Patient Reported Outcome (PRO) Questionnaires			
Did the subject complete the Smoker Screening Questionnaire prior to any study procedures being performed?			Yes / No
			YES

Section: Demog	7 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 07-02-2007	
Entered By: Sharon Ladenes		Entry Time: 22-05-2007 12:01:46	
		Last Modification Time: 22-05-2007 12:09:10	
		Page number: 5	
Demographics		Subject Initials	
Date of Birth	Gender	Height	Height Unit
(b) (6)	F	166.0	CM
		xxx.x	
		Weight	Weight Unit
		080.0	KG
		xxx.x	
Ethnicity			

CRF Report for Study E6270229

Patient: 2002
CRF: Screening
Visit: SCREENING

Site: CD_001
Blank? N
Visit Date: 07-02-2007

Investigator: RR_001
CRF Page #: 2
Document #: R142585313

Section: Demog		7 of 10	
Hispanic or Latino?	Race	Race other	
NO	WHITE		

Section: Vital		8 of 10		Blank? N		Section Status: Entry Complete	
Visit: SCREENING		Section Date: 07-02-2007		Entry Time: 22-05-2007 12:01:46			
Entered By: Sharon Ladenes		Last Modification Time: 22-05-2007 12:09:10		Page number: 5			
VITAL SIGNS							
Blood Pressure		Pulse		Respiratory Rate		Oral Temperature	
Actual Time	Systolic	Diastolic				Unit	
1045	135	086	068	16	35.1	C	
				xxx.x			
Comments							

Section: Hdyl_Oral_Health		9 of 10		Blank? N		Section Status: Entry Complete	
Visit: SCREENING		Section Date: 07-02-2007		Entry Time: 22-05-2007 12:01:46			
Entered By: Sharon Ladenes		Last Modification Time: 22-05-2007 12:09:10		Page number: 5			
HDYF? / ORAL HEALTH QUESTIONS INQUIRY							
		Oral Health Questions		Performed?		Comments	
Actual Time	HDYF Performed?						
NR	YES	YES					

Section: Lab_Eval		10 of 10		Blank? N		Section Status: Entry Complete	
Visit: SCREENING		Section Date: 07-02-2007		Entry Time: 22-05-2007 12:01:46			
Entered By: Sharon Ladenes		Last Modification Time: 22-05-2007 12:09:10		Page number: 6			
Laboratory Evaluations							
Were the scheduled laboratory samples obtained?		YES		No, specify			
Requisition Number 1		N526898					
Requisition Number 2 (if applicable)							
Were there any clinically significant labs?		NO		(Yes, specify below)			
Requisition Number	Test Name	H/L	Lab ID	Lab Name			

CRF Report for Study E6270229



Patient: 2002
CRF: Screening2
Visit: SCREENING
Entered By: Sharon Ladenes
Discrepancies: Closed
Approval Status: Not Approved
Verification: Not Verified
Comment:

Site: CD_001
Blank? N
Visit Date: 07-02-2007
Entry Time: 22-05-2007 12:09:48
Modification Time: 25-07-2007 15:34:50
Approval Time:
Verification Time:

Investigator: RR_001
CRF Page #: 3
Document #: R142587413
CRF Status: Entry Complete

Approver:
Verifier:

Section: Preg_Test	1 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 07-02-2007	
Entered By: Sharon Ladenes		Entry Time: 22-05-2007 12:09:48	
		Last Modification Time: 22-05-2007 12:19:20	
		Page number: 6	
Urine Pregnancy Test			
Result			
NEGA			
TIVE			

Section: Urine_Drug	2 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 07-02-2007	
Entered By: Sharon Ladenes		Entry Time: 22-05-2007 12:09:48	
		Last Modification Time: 22-05-2007 12:19:20	
		Page number: 6	
Urine Drug Screen			
Drug Screen Result			
NEG			

Section: Alcohol_Screen	3 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 07-02-2007	
Entered By: Sharon Ladenes		Entry Time: 22-05-2007 12:09:48	
		Last Modification Time: 22-05-2007 12:19:20	
		Page number: 6	
Breathalyzer Alcohol Screen			
Breathalyzer Result			
NEG			

Section: Med_Hx	4 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 07-02-2007	
Entered By: Sharon Ladenes		Entry Time: 22-05-2007 12:09:48	
		Last Modification Time: 22-05-2007 12:19:20	
		Page number: 7	

CRF Report for Study E6270229



Patient: 2002
CRF: Screening2
Visit: SCREENING

Site: CD_001
Blank? N
Visit Date: 07-02-2007

Investigator: RR_001
CRF Page #: 3
Document #: R142587413

Section: Med_Hx		4 of 10	
Medical History			
Does the subject have any relevant medical history?		YES	
If so, list the specific diagnosis and/or procedure.			
System	Diagnosis/Procedure	Date of Onset	Date of Resolution/Ongoing
SKIN			
EENT	NEAR & FARSIGHTED - WEARS CONTACTS	00-00-1985	ONGOING
BREASTS			
RESP	PNEUMONIA	00-00-2002	00-00-2002
CARDIO			
LYMPH/HEMA			
GASTRO			
GENITO	HYSTERECTOMY FOR IRREGULAR CYCLES	30-05-2005	30-05-2005
MUSCULO			
ENDOCRINE			
NEURO	MIGRAINE HEADACHES ONCE A MONTH	00-00-1986	ONGOING
IMMUNO			
PSYCH			
ALLERGIC			
OTHER			

Section: ECG		5 of 10		Blank? N		Section Status: Entry Complete	
Visit: SCREENING		Section Date: 07-02-2007					
Entered By: Sharon Ladenes		Entry Time: 22-05-2007 12:09:48					
		Last Modification Time: 22-05-2007 12:19:20					
		Page number: 8					
12-LEAD ELECTROCARDIOGRAM REPORT							
Actual Time		Ventricular Heart Rate					
1052		067					
Cardiac Cycle Measurements							
PR Interval		QRS Duration		QT Interval		QTc Interval	
144		079		416		439	
ECG INTERPRETATION:							
ANCS							
Comments (related to abnormal, CS findings only):							

Section: Usual_Brand_Cig		6 of 10		Blank? N		Section Status: Entry Complete	
Visit: SCREENING		Section Date: 07-02-2007					
Entered By: Sharon Ladenes		Entry Time: 22-05-2007 12:09:48					
		Last Modification Time: 12-07-2007 17:36:48					

CRF Report for Study E6270229

Patient: 2002
CRF: Screening2
Visit: SCREENING

Site: CD_001
Blank? N
Visit Date: 07-02-2007

Investigator: RR_001
CRF Page #: 3
Document #: R142587413

Section: Usual_Brand_Cig 6 of 10

Page number: 9

USUAL BRAND CIGARETTE PACK		DATA
Usual Brand	Type	Length
MARLBORO	MENTHOL	LONG 90-105MM
Style	Pack	How long have these been the subject's usual brand?
LIGHTS/LOW TAR	HARD	UNK months
		UNK years

Section: Ftc_Tar_Level 7 of 10

Blank? N

Section Status: Entry Complete

Visit: SCREENING
Entered By: Sharon Ladenes

Section Date: 07-02-2007
Entry Time: 22-05-2007 12:09:48
Last Modification Time: 16-07-2007 10:12:05
Page number: 9

FTC TAR LEVEL OF USUAL BRAND

FTC Tar Level (mg)
08.8

Section: Expired_Carbon_M 8 of 10

Blank? N

Section Status: Entry Complete

Visit: SCREENING
Entered By: Sharon Ladenes

Section Date: 07-02-2007
Entry Time: 22-05-2007 12:09:48
Last Modification Time: 22-05-2007 12:19:20
Page number: 10

EXPIRED CARBON MONOXIDE

Actual Time	ECO Level (ppm)	%COHb	Comments
1015	19	03.6	

Section: Best_Baseline_Sp 9 of 10

Blank? N

Section Status: Entry Complete

Visit: SCREENING
Entered By: Sharon Ladenes

Section Date: 07-02-2007
Entry Time: 22-05-2007 12:09:48
Last Modification Time: 22-05-2007 12:19:20
Page number: 10

BEST BASELINE SPIROMETRY TEST RESULT

Actual Time	FEV 1 Predicted	FVC Predicted	
of FEV1/FVC Test	(%)	(%)	Comments
1101	108	106	
Testing Position	FEV1 L	FVC L	
STANDING	3.40	4.11	

lrvs Training

10 10

N

Entry Complete

CRF Report for Study E6270229



Patient: 2002

CRF: Screening2

Visit: SCREENING

Site: CD_001

Blank? N

Visit Date: 07-02-2007

Investigator: RR_001

CRF Page #: 3

Document #: R142587413

Section: Irvs_Training

10 of 10

Blank?

Section Status:

Visit: SCREENING

Section Date: 07-02-2007

Entered By: Sharon Ladenaes

Entry Time: 22-05-2007 12:09:48

Last Modification Time: 22-05-2007 12:19:20

Page number: 10

IVRS TRAINING

Did Subject receive training on the Daily Call-In Diary (IVRS)?

YES

CRF Report for Study E6270229



Patient: 2002
CRF: Week-2
Visit: WEEK-2
Entered By: Sharon Ladenes
Discrepancies: None
Approval Status: Not Approved
Verification: Not Verified
Comment:

Site: CD_001
Blank? N
Visit Date: 07-02-2007
Entry Time: 22-05-2007 12:19:21
Modification Time: 22-05-2007 12:19:50
Approval Time:
Verification Time:

Investigator: RR_001
CRF Page #: 4
Document #: R142589313
CRF Status: Entry Complete

Approver:
Verifier:

Section: Usual_Brand_Coll	Blank? N	Section Status: Entry Complete								
Visit: WEEK -2	Section Date: 07-02-2007									
Entered By: Sharon Ladenes	Entry Time: 22-05-2007 12:19:21									
	Last Modification Time: 22-05-2007 12:19:50									
	Page number: 11									
<table><thead><tr><th>USUAL BRAND</th><th>CIGARETTE COLLECTION TRAINING</th></tr></thead><tbody><tr><td>1. Did subject receive foam block?</td><td>YES</td></tr><tr><td>2. Did subject receive training on usual brand collection?</td><td>YES</td></tr><tr><td>3. Was subject provided usual brand cigarettes for Week 0 cigarette butt collection?</td><td>YES</td></tr></tbody></table>			USUAL BRAND	CIGARETTE COLLECTION TRAINING	1. Did subject receive foam block?	YES	2. Did subject receive training on usual brand collection?	YES	3. Was subject provided usual brand cigarettes for Week 0 cigarette butt collection?	YES
USUAL BRAND	CIGARETTE COLLECTION TRAINING									
1. Did subject receive foam block?	YES									
2. Did subject receive training on usual brand collection?	YES									
3. Was subject provided usual brand cigarettes for Week 0 cigarette butt collection?	YES									

CRF Report for Study E6270229



Patient: 2002 Site: CD_001
CRF: Week 0 Baseline Blank? N
Visit: WEEK 0 (BASELINE) Visit Date: 06-03-2007
Entered By: Sharon Ladenes Entry Time: 21-05-2007 15:38:48
Discrepancies: None Modification Time: 04-12-2007 15:35:49
Approval Status: Not Approved Approval Time:
Verification: Not Verified Verification Time:
Comment:

Investigator: RR_001
CRF Page #: 5
Document #: R142486313
CRF Status: Entry Complete

Approver:
Verifier:

Section: Pro_Questionnaire	1 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 06-03-2007	
Entered By: Sharon Ladenes		Entry Time: 21-05-2007 15:38:48	
		Last Modification Time: 21-05-2007 15:49:59	
		Page number: 12A	

Date	PRO QUESTIONNAIRES	YES / NO
06-03-2007	1. With the possible exception of urinating, did subject complete Smoker Routine Questionnaire PRIOR to any study procedures being performed?	YES

Section: Urine_Drug	2 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 06-03-2007	
Entered By: Sharon Ladenes		Entry Time: 21-05-2007 15:38:48	
		Last Modification Time: 21-05-2007 15:49:59	
		Page number: 12A	

Date	Drug Screen	Drug Screen Result
06-03-2007		NEG

Section: Alcohol_Screen	3 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 06-03-2007	
Entered By: Sharon Ladenes		Entry Time: 21-05-2007 15:38:48	
		Last Modification Time: 21-05-2007 15:49:59	
		Page number: 12A	

Date	Alcohol Screen	Breathalyzer Result
06-03-2007		NEG

Section: Preg_Test	4 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 06-03-2007	
Entered By: Sharon Ladenes		Entry Time: 21-05-2007 15:38:48	
		Last Modification Time: 21-05-2007 15:49:59	
		Page number: 12A	

CRF Report for Study E6270229

Patient: 2002
CRF: Week 0 Baseline
Visit: WEEK 0 (BASELINE)

Site: CD_001
Blank? N
Visit Date: 06-03-2007

Investigator: RR_001
CRF Page #: 5
Document #: R142486313

Section: Preg_Test		4 of 11	
Pregnancy Test			
Date	Result		
06-03-2007	NEGA TIVE		

Section: Urine_Coll		5 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)		Section Date: 06-03-2007					
Entered By: Sharon Ladenes		Entry Time: 21-05-2007 15:38:48					
		Last Modification Time: 04-12-2007 15:35:49					
		Page number: 12A					
24-Hour Urine Collection							
Scheduled Timepoint	Start Date	Start Time	Stop Date	Stop Time	Total Volume	Comments	
SPOT URINE VOID	06-03-2007	1656	NA	NA	NA		
0 HOUR TO 24 HOURS	06-03-2007	1656	07-03-2007	1442	1300		

Section: Hdyf_Oral_Health		6 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)		Section Date: 06-03-2007					
Entered By: Sharon Ladenes		Entry Time: 21-05-2007 15:38:48					
		Last Modification Time: 04-12-2007 15:22:07					
		Page number: 13.1					
HDYF? INQUIRY							
Date	Actual Time	HDYF Performed?		Comments			
07-03-2007	0542	YES					

Section: Vital		7 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)		Section Date: 06-03-2007					
Entered By: Sharon Ladenes		Entry Time: 21-05-2007 15:38:48					
		Last Modification Time: 21-05-2007 15:49:59					
		Page number: 13.1					
VITAL SIGNS							
Blood Pressure							
Date	Actual Time	Systolic	Diastolic	Pulse	Respiratory Rate	Oral Temperature	Unit
06-03-2007	1533	119	080	065	18	ND xxx.x	ND
Comments							

CRF Report for Study E6270229



Patient: 2002

Site: CD_001

Investigator: RR_001

CRF: Week 0 Baseline

Blank? N

CRF Page #: 5

Visit: WEEK 0 (BASELINE)

Visit Date: 06-03-2007

Document #: R142486313

Section: Oral_Health_Exam	8 of 11	Blank? N
Visit: WEEK 0 (BASELINE)	Section Date: 06-03-2007	Section Status: Entry Complete
Entered By: Sharon Ladenes	Entry Time: 21-05-2007 15:38:48	
	Last Modification Time: 13-09-2007 15:51:24	
	Page number: 13.1	

ORAL HEALTH EXAMINATION

Date
06-03-2007

Procedure	Relevant Findings?*	Findings
ORAL HEALTH QUESTIONS PERFORMED	NO	
EVIDENCE OF LEUKOPLAKIA	NO	
OTHER ORAL KERATOSIS	NO	

Section: Phys_Exam	9 of 11	Blank? N
Visit: WEEK 0 (BASELINE)	Section Date: 06-03-2007	Section Status: Entry Complete
Entered By: Sharon Ladenes	Entry Time: 21-05-2007 15:38:48	
	Last Modification Time: 21-05-2007 15:49:59	
	Page number: 14.1	

PHYSICAL EXAMINATION

Date
06-03-2007

Code Number	Code	Relevant Findings?	Findings
01	GENERAL	NO	
02	SKIN	NO	
03	HEENT	NO	
04	MOUTH	NO	
05	NECK	NO	
06	THORAX/LUNG	NO	
07	CARDIO	NO	
08	ABDOMEN	NO	
09	MUSCULO	NO	
10	NEURO	NO	
11	LYMPH	NO	
12	OTHER	NE	

Section: Weight_Height	10 of 11	Blank? N
Visit: WEEK 0 (BASELINE)	Section Date: 06-03-2007	Section Status: Entry Complete
Entered By: Sharon Ladenes	Entry Time: 21-05-2007 15:38:48	
	Last Modification Time: 05-10-2007 12:37:08	
	Page number: 14.1	

CRF Report for Study E6270229

Patient: 2002

Site: CD_001

Investigator: RR_001

CRF: Week 0 Baseline

Blank? N

CRF Page #: 5

Visit: WEEK 0 (BASELINE)

Visit Date: 06-03-2007

Document #: R142486313

Section: Weight_Height 10 of 11

WEIGHT & HEIGHT

Date	Weight	Unit	Height	Unit
06-03-2007	082.5	KG	ND	CM
	xxx.x		xxx.x	

Section: Lab_Eval 11 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 06-03-2007

Entered By: Sharon Ladenes

Entry Time: 21-05-2007 15:38:48

Last Modification Time: 21-05-2007 15:49:59

Page number: 15.1

Laboratory Evaluations

Date					
06-03-2007					
Were the scheduled laboratory samples obtained?		YES	No, specify		
Requisition Number 1	N528056				
Requisition Number 2 (if applicable)	N526967				
Were there any clinically significant labs?	NO	(Yes, specify below)			
Requisition Number	Test Name	H/L	Lab ID	Lab Name	

CRF Report for Study E6270229



Patient: 2002 Site: CD_001
 CRF: Week 0 2baseline Blank? N
 Visit: WEEK 0 (BASELINE) Visit Date: 07-03-2007
 Entered By: Sharon Ladenes Entry Time: 21-05-2007 15:52:22
 Discrepancies: Closed Modification Time: 13-12-2007 15:57:45
 Approval Status: Not Approved Approval Time:
 Verification: Not Verified Verification Time:
 Comment:

Investigator: RR_001
 CRF Page #: 5.1
 Document #: R142488113
 CRF Status: Entry Complete

Approver:
 Verifier:

Section: Pk_Blood_Biomark	1 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 07-03-2007	
Entered By: Sharon Ladenes		Entry Time: 21-05-2007 15:52:22	
		Last Modification Time: 21-05-2007 16:04:11	
		Page number: 15.1	
Blood Sampling For Biomarkers/Chemistry/Hematology (following an overnight fast)			
Date	Actual Time	Comments	
07-03-2007	0624		

Section: Expired_Carbon_M	2 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 07-03-2007	
Entered By: Sharon Ladenes		Entry Time: 21-05-2007 15:52:22	
		Last Modification Time: 21-05-2007 16:04:11	
		Page number: 15.1	
EXPIRED CARBON MONOXIDE			
Date	Actual Time	ECO Level (ppm)	%COHb
07-03-2007	1514	8	01.9
Comments			

Section: Blood_SampL_Cohb	3 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 07-03-2007	
Entered By: Sharon Ladenes		Entry Time: 21-05-2007 15:52:22	
		Last Modification Time: 21-05-2007 16:04:11	
		Page number: 15.1	
Blood Sampling for %COHb			
Date	Actual Time	Comments	
07-03-2007	1516		

Section: Pre_Bronch_Spir	4 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 07-03-2007	
Entered By: Sharon Ladenes		Entry Time: 21-05-2007 15:52:22	
		Last Modification Time: 06-12-2007 18:47:31	
		Page number: 16.1	

CRF Report for Study E6270229

Patient: 2002

CRF: Week 0 2baseline

Visit: WEEK 0 (BASELINE)

Site: CD_001

Blank? N

Visit Date: 07-03-2007

Investigator: RR_001

CRF Page #: 5.1

Document #: R142488113

Section: Pre_Bronch_Spir		4 of 11					
PRE-BRONCHODILATOR BEST BASELINE SPIROMETRY TEST RESULT							
Actual Time							
of FEV1/FVC							
Date	Test	Testing Position	FEV1 L	FEV1 Predicted (%)	FVC L	FVC Predicted (%)	Comments
07-03-2007	1540	STANDI NG	3.48	111	4.28	111	

Section: Proventil_Admin		5 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)		Section Date: 07-03-2007					
Entered By: Sharon Ladenes		Entry Time: 21-05-2007 15:52:22					
		Last Modification Time: 21-05-2007 16:04:11					
		Page number: 16.1					
PROVENTIL ADMINISTRATION							
Actual Time							
of Proventil							
Date	Administration	Amount Administered		Comments			
07-03-2007	1604	2 METERED PUFFS					

Section: Post_Bronch_Spir		6 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)		Section Date: 07-03-2007					
Entered By: Sharon Ladenes		Entry Time: 21-05-2007 15:52:22					
		Last Modification Time: 13-12-2007 15:57:45					
		Page number: 16.1					
POST-BRONCHODILATOR BEST SPIROMETRY TEST RESULT							
Actual Time							
of FEV1/FVC							
Date	Test	Testing Position	FEV1 L	FEV1 Predicted (%)	FVC L	FVC Predicted (%)	Comments
07-03-2007	1630	STANDING	3.34	106	4.32	112	

Section: Unused_Usual_Bra		7 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)		Section Date: 07-03-2007					
Entered By: Sharon Ladenes		Entry Time: 21-05-2007 15:52:22					
		Last Modification Time: 21-05-2007 16:04:11					
		Page number: 17.1					
Unused Usual Brand Cigarette Pack Collection							
Yes / No							
Date	Does Site have 5 unopened packs of subject's usual brand cigarette to ship to CCLS?						YES
07-03-2007							

CRF Report for Study E6270229



Patient: 2002
CRF: Week 0 2baseline
Visit: WEEK 0 (BASELINE)

Site: CD_001
Blank? N
Visit Date: 07-03-2007

Investigator: RR_001
CRF Page #: 5.1
Document #: R142488113

Section: Usual_Brand_Butt		8 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)		Section Date: 07-03-2007		Entry Time: 21-05-2007 15:52:22			
Entered By: Sharon Ladenes		Last Modification Time: 21-05-2007 16:04:11		Page number: 17.1			

Usual Brand Cigarette Butt Collection					Number of Usual Brand Cigarette Butts Collected	Any Product Deviation?	If yes, number of butts other than usual brand:	Comments
Scheduled Collection Period	Start Date	Start Time	Stop Date	Stop Time				
24 HOURS PRIOR TO CHECK-IN	05-03- 2007	1400	06-03-2007	1400	18	NO		
24 HOURS IN-HOUSE	06-03- 2007	1400	07-03-2007	1400	9	NO		

Section: Used_Butt_Measur		9 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)		Section Date: 07-03-2007		Entry Time: 21-05-2007 15:52:22			
Entered By: Sharon Ladenes		Last Modification Time: 21-05-2007 16:04:11		Page number: 18.1			

USUAL BRAND CIGARETTE BUTT MEASUREMENT			
Date	Scheduled Collection Period	Cigarette Butt Number	Cigarette Butt Measurement (mm)
05-03-2007	24 HOURS PRIOR TO CHECK-IN	1	40
		2	43
		3	41
		4	43
		5	40
		6	42
		7	41
		8	40
		9	42
		10	38
		11	45
		12	43
		13	36
		14	43
		15	43
		16	43
		17	44

CRF Report for Study E6270229

Patient: 2002

CRF: Week 0 2baseline

Visit: WEEK 0 (BASELINE)

Site: CD_001

Blank? N

Visit Date: 07-03-2007

Investigator: RR_001

CRF Page #: 5.1

Document #: R142488113

Section: Used_Butt_Measur 9 of 11

18

42

Section: Used_Butt_Measur 10 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 07-03-2007

Entered By: Sharon Ladenes

Entry Time: 21-05-2007 15:52:22

Last Modification Time: 21-05-2007 16:04:11

Page number: 19.1

USUAL BRAND CIGARETTE BUTT MEASUREMENT

Scheduled Collection

Date
06-03-2007

Period
24 HOURS IN-HOUSE

Cigarette Butt Number

Cigarette Butt Measurement (mm)

1

44

2

42

3

40

4

40

5

44

6

41

7

41

8

44

9

46

Section: Randomization 11 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 07-03-2007

Entered By: Sharon Ladenes

Entry Time: 21-05-2007 15:52:22

Last Modification Time: 21-05-2007 16:04:11

Page number: 20.1

RANDOMIZATION

Date
07-03-2007

Actual Time
1803

Randomization Sequence
GROUP B

CRF Report for Study E6270229

Patient: 2002

CRF: Week 0 3baseline

Visit: WEEK 0 (BASELINE)

Entered By: Sharon Ladenes

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CD_001

Blank? N

Visit Date: 07-03-2007

Entry Time: 21-05-2007 16:04:12

Modification Time: 07-01-2008 18:06:55

Approval Time:

Verification Time:

Investigator: RR_001

CRF Page #: 5.2

Document #: R142488213

CRF Status: Entry Complete

Approver:

Verifier:

Section: Study_Prod_Dispe

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 07-03-2007

Entered By: Sharon Ladenes

Entry Time: 21-05-2007 16:04:12

Last Modification Time: 07-12-2007 15:39:16

Page number: 23.1

STUDY PRODUCT DISPENSATION

Date	Actual Time	Product Dispensed	Flavor	Amount Dispensed
07-03-2007	1900	SNUS	ORIGINAL	1
07-03-2007	1900	SNUS	FROST	62
07-03-2007	1900	SNUS	SPICE	60

CRF Report for Study E6270229



Patient: 2002

CRF: Intercurrent_III

Visit: INTERCURRENT ILL

Entered By: Sharon Ladenes

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CD_001

Blank? N

Visit Date: 13-03-2007

Entry Time: 12-07-2007 18:11:51

Modification Time: 12-09-2007 13:13:55

Approval Time:

Verification Time:

Investigator: RR_001

CRF Page #: 7

Document #: R148447513

CRF Status: Entry Complete

Approver:

Verifier:

Section: Ip_Findings

Blank? N

Section Status: Entry Complete

Visit: INTERCURRENT ILL

Section Date: 13-03-2007

Entered By: Sharon Ladenes

Entry Time: 12-07-2007 18:11:51

Last Modification Time: 12-09-2007 13:13:55

Page number: 21

Intercurrent Illness/Physical Findings

Did the subject experience any intercurrent illness/findings from Screening to the first use of study product?

NO

Onset

Resolved / Changed

Relationship

Event No

Illness/Finding

Date

Time

Date

Time

Severity

to Procedure

Action Taken

CRF Report for Study E6270229



Patient: 2002
 CRF: Week 1
 Visit: WEEK 1
 Entered By: Sharon Ladenes
 Discrepancies: None
 Approval Status: Not Approved
 Verification: Not Verified
 Comment:

Site: CD_001
 Blank? N
 Visit Date: 13-03-2007
 Entry Time: 21-05-2007 16:10:21
 Modification Time: 07-01-2008 18:06:55
 Approval Time:
 Verification Time:

Investigator: RR_001
 CRF Page #: 8
 Document #: R142488513
 CRF Status: Entry Complete
 Approver:
 Verifier:

Section: HdyL_Oral_Health		1 of 5		Blank? N		Section Status: Entry Complete	
Visit: WEEK 1				Section Date: 13-03-2007			
Entered By: Sharon Ladenes				Entry Time: 21-05-2007 16:10:21			
				Last Modification Time: 21-05-2007 16:11:35			
				Page number: 22			
HDYF? / ORAL HEALTH QUESTIONS INQUIRY							
				Oral Health Questions			
Actual Time		HDYF Performed?		Performed?		Comments	
NR		YES		YES			

Section: Vital		2 of 5		Blank? N		Section Status: Entry Complete	
Visit: WEEK 1				Section Date: 13-03-2007			
Entered By: Sharon Ladenes				Entry Time: 21-05-2007 16:10:21			
				Last Modification Time: 21-05-2007 16:11:35			
				Page number: 22			
VITAL SIGNS							
		Blood Pressure				Oral	
Actual Time	Systolic	Diastolic	Pulse	Respiratory Rate	Temperature	Unit	
1331	108	058	072	16	035.7	C	
				xxx.x			
Comments							

Section: Expired_Carbon_M		3 of 5		Blank? N		Section Status: Entry Complete	
Visit: WEEK 1				Section Date: 13-03-2007			
Entered By: Sharon Ladenes				Entry Time: 21-05-2007 16:10:21			
				Last Modification Time: 21-05-2007 16:11:35			
				Page number: 22			
EXPIRED CARBON MONOXIDE							
Actual Time	ECO Level (ppm)		%COHb		Comments		
1334	9		02.0				

Section: Unused_Study_Pro		4 of 5		Blank? N		Section Status: Entry Complete	
---------------------------	--	--------	--	----------	--	--------------------------------	--

CRF Report for Study E6270229



Patient: 2002
CRF: Week 1
Visit: WEEK 1

Site: CD_001
Blank? N
Visit Date: 13-03-2007

Investigator: RR_001
CRF Page #: 8
Document #: R142488513

Section: Unused_Study_Pro	4 of 5	Section Date: 13-03-2007
Visit: WEEK 1		Entry Time: 21-05-2007 16:10:21
Entered By: Sharon Ladenes		Last Modification Time: 07-01-2008 15:43:01
Page number: 23		

Unused Study Product Returned		Amount Returned	
Product Returned	Flavor	Packs	Individual Cigarettes / pouches
SNUS	ORIGINAL		53
SNUS	FROST		00
SNUS	SPICE		00

Section: Study_Prod_Dispe	5 of 5	Blank? N	Section Status: Entry Complete
Visit: WEEK 1		Section Date: 13-03-2007	
Entered By: Sharon Ladenes		Entry Time: 21-05-2007 16:10:21	
		Last Modification Time: 05-10-2007 13:21:39	
Page number: 23			

STUDY PRODUCT DISPENSATION			
Actual Time	Product Dispensed	Flavor	Amount Dispensed
NA	SNUS	ORIGINAL	00
NA	SNUS	FROST	00
NA	SNUS	SPICE	00

CRF Report for Study E6270229

Patient: 2002

CRF: Week 2

Visit: WEEK 2

Entered By: Sharon Ladenes

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CD_001

Blank? Y

Visit Date: 20-03-2007

Entry Time: 21-05-2007 16:11:48

Modification Time:

Approval Time:

Verification Time:

Investigator: RR_001

CRF Page #: 9

Document #: R142488713

CRF Status: Created

Approver:

Verifier:

Section: HDyf_Oral_Health	1 of 6	Blank? Y	Section Status: Created
Visit: WEEK 2		Section Date: 20-03-2007	
Entered By: Sharon Ladenes		Entry Time: 21-05-2007 16:11:48	
		Last Modification Time:	
		Page number: 24	
HDYF? / ORAL HEALTH QUESTIONS INQUIRY			
		Oral Health Questions	
Actual Time	HDYF Performed?	Performed?	Comments

Section: Vital	2 of 6	Blank? Y	Section Status: Created
Visit: WEEK 2		Section Date: 20-03-2007	
Entered By: Sharon Ladenes		Entry Time: 21-05-2007 16:11:48	
		Last Modification Time:	
		Page number: 24	
VITAL SIGNS			
Actual Time	Blood Pressure Systolic Diastolic	Pulse Respiratory Rate	Oral Temperature xxx.x
Unit			
Comments			

Section: Expired_Carbon_M	3 of 6	Blank? Y	Section Status: Created
Visit: WEEK 2		Section Date: 20-03-2007	
Entered By: Sharon Ladenes		Entry Time: 21-05-2007 16:11:48	
		Last Modification Time:	
		Page number: 24	
EXPIRED CARBON MONOXIDE			
Actual Time	ECO Level (ppm)	%COHb	Comments

Section: Blood_SampL_Cohb	4 of 6	Blank? Y	Section Status: Created
Visit: WEEK 2		Section Date: 20-03-2007	
Entered By: Sharon Ladenes		Entry Time: 21-05-2007 16:11:48	
		Last Modification Time:	

CRF Report for Study E6270229

Patient: 2002
CRF: Week 2
Visit: WEEK 2

Site: CD_001
Blank? Y
Visit Date: 20-03-2007

Investigator: RR_001
CRF Page #: 9
Document #: R142488713

Section: Blood_Sampl_Cohb	4 of 6	Page number: 24
Blood Sampling for %COHb		
Actual Time	Comments	

Section: Unused_Study_Pro	5 of 6	Blank? Y	Section Status: Created
Visit: WEEK 2	Section Date: 20-03-2007		
Entered By: Sharon Ladenes	Entry Time: 21-05-2007 16:11:48		
Last Modification Time:			
Page number: 25			
Unused Study Product Returned			
Product Returned	Flavor	Amount Returned	
		Packs	Individual Cigarettes / pouches

Section: Study_Prod_Dispe	6 of 6	Blank? Y	Section Status: Created
Visit: WEEK 2	Section Date: 20-03-2007		
Entered By: Sharon Ladenes	Entry Time: 21-05-2007 16:11:48		
Last Modification Time:			
Page number: 25			
STUDY PRODUCT DISPENSATION			
Actual Time	Product Dispensed	Flavor	Amount Dispensed

CRF Report for Study E6270229



Patient: 2002	Site: CD_001	Investigator: RR_001
CRF: Week 4	Blank? Y	CRF Page #: 10
Visit: WEEK 4	Visit Date: 03-04-2007	Document #: R160350913
Entered By: Sharon Ladenes	Entry Time: 05-10-2007 13:23:13	CRF Status: Created
Discrepancies: None	Modification Time:	Approver:
Approval Status: Not Approved	Approval Time:	Verifier:
Verification: Not Verified	Verification Time:	
Comment:		

Section: Pro_Questionnair	1 of 6	Blank? Y	Section Status: Created
Visit: WEEK 4		Section Date: 03-04-2007	
Entered By: Sharon Ladenes		Entry Time: 05-10-2007 13:23:13	
		Last Modification Time:	
		Page number: 26	
PRO QUESTIONNAIRES			
With the possible exception of urinating, did subject complete Smoker Core Questionnaire PRIOR to any study procedures being performed?			YES / NO

Section: Hdyf_Oral_Health	2 of 6	Blank? Y	Section Status: Created
Visit: WEEK 4		Section Date: 03-04-2007	
Entered By: Sharon Ladenes		Entry Time: 05-10-2007 13:23:13	
		Last Modification Time:	
		Page number: 26	
HDYF? / ORAL HEALTH QUESTIONS INQUIRY			
Oral Health Questions			
Actual Time	HDYF Performed?	Performed?	Comments

Section: Vital	3 of 6	Blank? Y	Section Status: Created
Visit: WEEK 4		Section Date: 03-04-2007	
Entered By: Sharon Ladenes		Entry Time: 05-10-2007 13:23:13	
		Last Modification Time:	
		Page number: 26	
VITAL SIGNS			
Actual Time	Blood Pressure	Pulse	Respiratory Rate
	Systolic	Diastolic	Temperature
			xxx.x
Unit			
Comments			

Section: Expired_Carbon_M	4 of 6	Blank? Y	Section Status: Created
Visit: WEEK 4		Section Date: 03-04-2007	

CRF Report for Study E6270229

Patient: 2002
CRF: Week 4
Visit: WEEK 4

Site: CD_001
Blank? Y
Visit Date: 03-04-2007

Investigator: RR_001
CRF Page #: 10
Document #: R160350913

Section: Expired_Carbon_M 4 of 6

Entered By: Sharon Ladenes

Entry Time: 05-10-2007 13:23:13

Last Modification Time:

Page number: 26

EXPIRED CARBON MONOXIDE

Actual Time	ECO Level (ppm)	%COHb	Comments
-------------	-----------------	-------	----------

Section: Unused_Study_Pro 5 of 6

Blank? Y

Section Status: Created

Visit: WEEK 4

Section Date: 03-04-2007

Entered By: Sharon Ladenes

Entry Time: 05-10-2007 13:23:13

Last Modification Time:

Page number: 27

Unused Study Product Returned

Product Returned	Flavor	Amount Returned	
		Packs	Individual Cigarettes / pouches

Section: Study_Prod_Dispe 6 of 6

Blank? Y

Section Status: Created

Visit: WEEK 4

Section Date: 03-04-2007

Entered By: Sharon Ladenes

Entry Time: 05-10-2007 13:23:13

Last Modification Time:

Page number: 27

STUDY PRODUCT DISPENSATION

Actual Time	Product Dispensed	Flavor	Amount Dispensed
-------------	-------------------	--------	------------------

CRF Report for Study E6270229



Patient: 2002	Site: CD_001	Investigator: RR_001
CRF: Week 6	Blank? Y	CRF Page #: 11
Visit: WEEK 6	Visit Date: 01-05-2007	Document #: R160352013
Entered By: Sharon Ladenes	Entry Time: 05-10-2007 13:29:01	CRF Status: Created
Discrepancies: None	Modification Time:	
Approval Status: Not Approved	Approval Time:	Approver:
Verification: Not Verified	Verification Time:	Verifier:
Comment:		

Section: HDyf_Oral_Health	1 of 5	Blank? Y	Section Status: Created
Visit: WEEK 6		Section Date: 01-05-2007	
Entered By: Sharon Ladenes		Entry Time: 05-10-2007 13:29:01	
		Last Modification Time:	
		Page number: 28	
HDYF? / ORAL HEALTH QUESTIONS INQUIRY			
		Oral Health Questions	
Actual Time	HDYF Performed?	Performed?	Comments

Section: Expired_Carbon_M	2 of 5	Blank? Y	Section Status: Created
Visit: WEEK 6		Section Date: 01-05-2007	
Entered By: Sharon Ladenes		Entry Time: 05-10-2007 13:29:01	
		Last Modification Time:	
		Page number: 28	
EXPIRED CARBON MONOXIDE			
Actual Time	ECO Level (ppm)	%COHb	Comments

Section: Vital	3 of 5	Blank? Y	Section Status: Created
Visit: WEEK 6		Section Date: 01-05-2007	
Entered By: Sharon Ladenes		Entry Time: 05-10-2007 13:29:01	
		Last Modification Time:	
		Page number: 28	
VITAL SIGNS			
Actual Time	Blood Pressure	Pulse	Respiratory Rate
	Systolic	Diastolic	Temperature
			xxx.x
Unit			
Comments			

Section: Unused_Study_Pro	4 of 5	Blank? Y	Section Status: Created
Visit: WEEK 6		Section Date: 01-05-2007	
Entered By: Sharon Ladenes		Entry Time: 05-10-2007 13:29:01	
		Last Modification Time:	

CRF Report for Study E6270229

Patient: 2002
CRF: Week 6
Visit: WEEK 6

Site: CD_001
Blank? Y
Visit Date: 01-05-2007

Investigator: RR_001
CRF Page #: 11
Document #: R160352013

Section: Unused_Study_Pro 4 of 5

Page number: 29

Unused Study Product Returned

Product Returned	Flavor	Amount Returned	
		Packs	Individual Cigarettes / pouches

Section: Study_Prod_Dispe 5 of 5

Blank? Y

Section Status: Created

Visit: WEEK 6

Section Date: 01-05-2007

Entered By: Sharon Ladenes

Entry Time: 05-10-2007 13:29:01

Last Modification Time:

Page number: 29

STUDY PRODUCT DISPENSATION

Actual Time	Product Dispensed	Flavor	Amount Dispensed
-------------	-------------------	--------	------------------

CRF Report for Study E6270229



Patient: 2002	Site: CD_001	Investigator: RR_001
CRF: Week 8	Blank? Y	CRF Page #: 13
Visit: WEEK 8	Visit Date: 01-05-2007	Document #: R160571313
Entered By: Sharon Ladenes	Entry Time: 08-10-2007 21:55:14	CRF Status: Created
Discrepancies: None	Modification Time:	Approver:
Approval Status: Not Approved	Approval Time:	Verifier:
Verification: Not Verified	Verification Time:	
Comment:		

Section: Pro_Questionnaire	1 of 6	Blank? Y	Section Status: Created
Visit: WEEK 8		Section Date: 01-05-2007	
Entered By: Sharon Ladenes		Entry Time: 08-10-2007 21:55:14	
		Last Modification Time:	
		Page number: 30	
PRO QUESTIONNAIRES			
With the possible exception of urinating, did subject complete Smoker Core Questionnaire PRIOR to any study procedures being performed?			YES / NO

Section: Hdyl_Oral_Health	2 of 6	Blank? Y	Section Status: Created
Visit: WEEK 8		Section Date: 01-05-2007	
Entered By: Sharon Ladenes		Entry Time: 08-10-2007 21:55:14	
		Last Modification Time:	
		Page number: 30	
HDYF? / ORAL HEALTH QUESTIONS INQUIRY			
		Oral Health Questions	
Actual Time	HDYF Performed?	Performed?	Comments

Section: Vital	3 of 6	Blank? Y	Section Status: Created
Visit: WEEK 8		Section Date: 01-05-2007	
Entered By: Sharon Ladenes		Entry Time: 08-10-2007 21:55:14	
		Last Modification Time:	
		Page number: 30	
VITAL SIGNS			
Actual Time	Blood Pressure	Pulse	Respiratory Rate
	Systolic	Diastolic	Oral Temperature
			xxx.x
Unit			
Comments			

Section: Expired_Carbon_M	4 of 6	Blank? Y	Section Status: Created
Visit: WEEK 8		Section Date: 01-05-2007	

CRF Report for Study E6270229



Patient: 2002
CRF: Week 8
Visit: WEEK 8

Site: CD_001
Blank? Y
Visit Date: 01-05-2007

Investigator: RR_001
CRF Page #: 13
Document #: R160571313

Section: Expired_Carbon_M	4 of 6		
Entered By: Sharon Ladenes	Entry Time: 08-10-2007 21:55:14		
Last Modification Time:			
Page number: 30			
EXPIRED CARBON MONOXIDE			
Actual Time	ECO Level (ppm)	%COHb	Comments

Section: Unused_Study_Pro	5 of 6	Blank? Y	Section Status: Created
Visit: WEEK 8	Section Date: 01-05-2007		
Entered By: Sharon Ladenes	Entry Time: 08-10-2007 21:55:14		
Last Modification Time:			
Page number: 31			
Unused Study Product Returned			
Product Returned	Flavor	Amount Returned	
		Packs	Individual Cigarettes / pouches

Section: Study_Prod_Dispe	6 of 6	Blank? Y	Section Status: Created
Visit: WEEK 8	Section Date: 01-05-2007		
Entered By: Sharon Ladenes	Entry Time: 08-10-2007 21:55:14		
Last Modification Time:			
Page number: 31			
STUDY PRODUCT DISPENSATION			
Actual Time	Product Dispensed	Flavor	Amount Dispensed

CRF Report for Study E6270229



Patient: 2002	Site: CD_001	Investigator: RR_001
CRF: Week 10	Blank? Y	CRF Page #: 14
Visit: WEEK 10	Visit Date: 15-05-2007	Document #: R160352413
Entered By: Sharon Ladenes	Entry Time: 05-10-2007 13:29:43	CRF Status: Created
Discrepancies: None	Modification Time:	Approver:
Approval Status: Not Approved	Approval Time:	Verifier:
Verification: Not Verified	Verification Time:	
Comment:		

Section: Hdy_Oral_Health	1 of 5	Blank? Y	Section Status: Created
Visit: WEEK 10		Section Date: 15-05-2007	
Entered By: Sharon Ladenes		Entry Time: 05-10-2007 13:29:43	
		Last Modification Time:	
		Page number: 32	
HDYF? / ORAL HEALTH QUESTIONS INQUIRY			
		Oral Health Questions	
Actual Time	HDYF Performed?	Performed?	Comments

Section: Expired_Carbon_M	2 of 5	Blank? Y	Section Status: Created
Visit: WEEK 10		Section Date: 15-05-2007	
Entered By: Sharon Ladenes		Entry Time: 05-10-2007 13:29:43	
		Last Modification Time:	
		Page number: 32	
EXPIRED CARBON MONOXIDE			
Actual Time	ECO Level (ppm)	%COHb	Comments

Section: Vital	3 of 5	Blank? Y	Section Status: Created
Visit: WEEK 10		Section Date: 15-05-2007	
Entered By: Sharon Ladenes		Entry Time: 05-10-2007 13:29:43	
		Last Modification Time:	
		Page number: 32	
VITAL SIGNS			
Actual Time	Blood Pressure	Pulse	Respiratory Rate
	Systolic	Diastolic	Temperature
			xxx.x
Comments			Unit

Section: Unused_Study_Pro	4 of 5	Blank? Y	Section Status: Created
Visit: WEEK 10		Section Date: 15-05-2007	
Entered By: Sharon Ladenes		Entry Time: 05-10-2007 13:29:43	
		Last Modification Time:	

CRF Report for Study E6270229

Patient: 2002

CRF: Week 10

Visit: WEEK 10

Site: CD_001

Blank? Y

Visit Date: 15-05-2007

Investigator: RR_001

CRF Page #: 14

Document #: R160352413

Section: Unused_Study_Pro 4 of 5

Page number: 33

Unused Study Product Returned

Product Returned

Flavor

Amount Returned

Packs

Individual Cigarettes / pouches

Section: Study_Prod_Dispe

5 of 5

Blank? Y

Section Status: Created

Visit: WEEK 10

Section Date: 15-05-2007

Entered By: Sharon Ladenes

Entry Time: 05-10-2007 13:29:43

Last Modification Time:

Page number: 33

STUDY PRODUCT DISPENSATION

Actual Time

Product Dispensed

Flavor

Amount Dispensed

CRF Report for Study E6270229



Patient: 2002	Site: CD_001	Investigator: RR_001
CRF: Week 12	Blank? Y	CRF Page #: 15
Visit: WEEK 12	Visit Date: 29-05-2007	Document #: R160352513
Entered By: Sharon Ladenes	Entry Time: 05-10-2007 13:30:00	CRF Status: Created
Discrepancies: None	Modification Time:	
Approval Status: Not Approved	Approval Time:	Approver:
Verification: Not Verified	Verification Time:	Verifier:
Comment:		

Section: Pro_Questionnaire	1 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 29-05-2007	
Entered By: Sharon Ladenes		Entry Time: 05-10-2007 13:30:00	
		Last Modification Time:	
		Page number: 34	
PRO QUESTIONNAIRES			
Date	1. With the possible exception of urinating, did subject complete Smoker Routine Questionnaire PRIOR to any study procedures being performed?	YES / NO	

Section: Urine_Drug	2 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 29-05-2007	
Entered By: Sharon Ladenes		Entry Time: 05-10-2007 13:30:00	
		Last Modification Time:	
		Page number: 34	
Drug Screen			
Date	Drug Screen Result		

Section: Alcohol_Screen	3 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 29-05-2007	
Entered By: Sharon Ladenes		Entry Time: 05-10-2007 13:30:00	
		Last Modification Time:	
		Page number: 34	
Alcohol Screen			
Date	Breathalyzer Result		

Section: Preg_Test	4 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 29-05-2007	
Entered By: Sharon Ladenes		Entry Time: 05-10-2007 13:30:00	
		Last Modification Time:	
		Page number: 34	
Pregnancy Test			

CRF Report for Study E6270229

Patient: 2002
CRF: Week 12
Visit: WEEK 12

Site: CD_001
Blank? Y
Visit Date: 29-05-2007

Investigator: RR_001
CRF Page #: 15
Document #: R160352513

Section: Preg_Test	4 of 11
Date	Result

Section: Urine_Coll	5 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12	Section Date: 29-05-2007	Entry Time: 05-10-2007 13:30:00	
Entered By: Sharon Ladenes	Last Modification Time:	Page number: 34	
24-Hour Urine Collection			
Scheduled Timepoint	Start Date	Start Time	Stop Date
		Stop Time	Total Volume
			Comments

Section: Hdyf_Oral_Health	6 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12	Section Date: 29-05-2007	Entry Time: 05-10-2007 13:30:00	
Entered By: Sharon Ladenes	Last Modification Time:	Page number: 35	
HDYF? INQUIRY			
Date	Actual Time	HDYF Performed?	Comments

Section: Vital	7 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12	Section Date: 29-05-2007	Entry Time: 05-10-2007 13:30:00	
Entered By: Sharon Ladenes	Last Modification Time:	Page number: 35	
VITAL SIGNS			
		Blood Pressure	Oral Temperature
Date	Actual Time	Systolic	Diastolic
		Pulse	Respiratory Rate
			Unit
			xxx.x
Comments			

Section: Oral_Health_Exam	8 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12	Section Date: 29-05-2007	Entry Time: 05-10-2007 13:30:00	
Entered By: Sharon Ladenes	Last Modification Time:	Page number: 35	
ORAL HEALTH EXAMINATION			

CRF Report for Study E6270229



Patient: 2002
CRF: Week 12
Visit: WEEK 12

Site: CD_001
Blank? Y
Visit Date: 29-05-2007

Investigator: RR_001
CRF Page #: 15
Document #: R160352513

Section: Oral_Health_Exam		8 of 11	
Date	Procedure	Relevant Findings?*	Findings

Section: Phys_Exam		9 of 11		Blank? Y		Section Status: Created	
Visit: WEEK 12		Section Date: 29-05-2007		Entry Time: 05-10-2007 13:30:00			
Entered By: Sharon Ladenes		Last Modification Time:		Page number: 36			
PHYSICAL EXAMINATION							
Date	Code Number	Code	Relevant Findings?	Findings			

Section: Weight_Height		10 of 11		Blank? Y		Section Status: Created	
Visit: WEEK 12		Section Date: 29-05-2007		Entry Time: 05-10-2007 13:30:00			
Entered By: Sharon Ladenes		Last Modification Time:		Page number: 36			
WEIGHT & HEIGHT							
Date	Weight xxx.x	Unit	Height xxx.x	Unit			

Section: Lab_Eval		11 of 11		Blank? Y		Section Status: Created	
Visit: WEEK 12		Section Date: 29-05-2007		Entry Time: 05-10-2007 13:30:00			
Entered By: Sharon Ladenes		Last Modification Time:		Page number: 37			
Laboratory Evaluations							
Date	Were the scheduled laboratory samples obtained?			No, specify			
	Requisition Number 1						
	Requisition Number 2 (if applicable)						
	Were there any clinically significant labs?			(Yes, specify below)			
Requisition Number	Test Name	H/L	Lab ID	Lab Name			

CRF Report for Study E6270229



Patient: 2002	Site: CD_001	Investigator: RR_001
CRF: Week 12(2)	Blank? Y	CRF Page #: 16
Visit: WEEK 12	Visit Date: 29-05-2007	Document #: R160352613
Entered By: Sharon Ladenes	Entry Time: 05-10-2007 13:30:20	CRF Status: Created
Discrepancies: None	Modification Time:	Approver:
Approval Status: Not Approved	Approval Time:	Verifier:
Verification: Not Verified	Verification Time:	
Comment:		

Section: Pk_Blood_Biomark	1 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 29-05-2007	
Entered By: Sharon Ladenes		Entry Time: 05-10-2007 13:30:20	
		Last Modification Time:	
		Page number: 37	
Blood Sampling For Biomarkers/Chemistry/Hematology (following an overnight fast)			
Date	Actual Time	Comments	

Section: Expired_Carbon_M	2 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 29-05-2007	
Entered By: Sharon Ladenes		Entry Time: 05-10-2007 13:30:20	
		Last Modification Time:	
		Page number: 37	
EXPIRED CARBON MONOXIDE			
Date	Actual Time	ECO Level (ppm)	%COHb
			Comments

Section: Blood_Sampl_Cohb	3 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 29-05-2007	
Entered By: Sharon Ladenes		Entry Time: 05-10-2007 13:30:20	
		Last Modification Time:	
		Page number: 37	
Blood Sampling for %COHb			
Date	Actual Time	Comments	

Section: Pre_Bronch_Spir	4 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 29-05-2007	
Entered By: Sharon Ladenes		Entry Time: 05-10-2007 13:30:20	
		Last Modification Time:	
		Page number: 38	
PRE-BRONCHODILATOR BEST BASELINE SPIROMETRY TEST RESULT			
Actual Time			

CRF Report for Study E6270229

Patient: 2002
CRF: Week 12(2)
Visit: WEEK 12

Site: CD_001
Blank? Y
Visit Date: 29-05-2007

Investigator: RR_001
CRF Page #: 16
Document #: R160352613

Section: Pre_Bronch_Spir	4 of 11						
Date	of FEV1/FVC Test	Testing Position	FEV1 L	FEV1 Predicted (%)	FVC L	FVC Predicted (%)	Comments

Section: Proventil_Admin	5 of 11	Blank? Y	Section Date: 29-05-2007	Section Status: Created
Visit: WEEK 12		Entry Time: 05-10-2007 13:30:20		
Entered By: Sharon Ladenes		Last Modification Time:		
		Page number: 38		
PROVENTIL ADMINISTRATION				
Date	Actual Time of Proventil Administration	Amount Administered		Comments

Section: Post_Bronch_Spir	6 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 29-05-2007	
Entered By: Sharon Ladenes		Entry Time: 05-10-2007 13:30:20	
		Last Modification Time:	
		Page number: 38	
POST-BRONCHODILATOR BEST SPIROMETRY TEST RESULT			
	Actual Time of FEV1/FVC	Testing Position	
Date	Test	FEV1 L	FEV1 Predicted (%)
		FVC L	FVC Predicted (%)
			Comments

Section: Used_Study_Tobac	7 of 11	Blank? Y	Section Status: Created						
Visit: WEEK 12		Section Date: 29-05-2007							
Entered By: Sharon Ladenes		Entry Time: 05-10-2007 13:30:20							
		Last Modification Time:							
		Page number: 39							
USED STUDY TOBACCO-HEATING CIGARETTE COLLECTION									
Scheduled Collection		Number of Study Tobacco-Heating	Weight of						
Timepoint	Start Date	Start Time	Stop Date	Stop Time	Cigarettes Collected	Cigarettes Collected (g)	Any Product Deviation?	If yes, # of other Brand	Comments

Section: Used_Study_Snus	8 of 11	Blank? Y	Section Date: 29-05-2007	Section Status: Created
Visit: WEEK 12		Entry Time: 05-10-2007 13:30:20		
Entered By: Sharon Ladenes				

CRF Report for Study E6270229



Patient: 2002
CRF: Week 12(2)
Visit: WEEK 12

Site: CD_001
Blank? Y
Visit Date: 29-05-2007

Investigator: RR_001
CRF Page #: 16
Document #: R160352613

Section: Used_Study_Snus 8 of 11

Last Modification Time:
Page number: 40

USED STUDY SNUS COLLECTION

Scheduled Collection Timepoint	Start Date	Start Time	Stop Date	Stop Time	Number of Study Pouches Collected	Any Product Deviation?	If Yes, # of other brand:	Comments
-----------------------------------	------------	------------	-----------	-----------	--------------------------------------	---------------------------	------------------------------	----------

Section: Used_Study_Burn 9 of 11

Blank? Y

Section Status: Created

Visit: WEEK 12

Section Date: 29-05-2007

Entered By: Sharon Ladenes

Entry Time: 05-10-2007 13:30:20

Last Modification Time:

Page number: 41

USED STUDY TOBACCO-BURNING CIGARETTE COLLECTION

Scheduled Collection Timepoint	Start Date	Start Time	Stop Date	Stop Time	Number of Study Tobacco- Burning Cigarettes Collected	Any Product Deviation?	If Yes, # of other brand:	Comments
-----------------------------------	------------	------------	-----------	-----------	---	---------------------------	------------------------------	----------

Section: Used_Butt_Measur 10 of 11

Blank? Y

Section Status: Created

Visit: WEEK 12

Section Date: 29-05-2007

Entered By: Sharon Ladenes

Entry Time: 05-10-2007 13:30:20

Last Modification Time:

Page number: 42

USUAL STUDY TOBACCO-BURNING CIGARETTE BUTT MEASUREMENT

Date	Scheduled Collection Period	Cigarette Butt Number	Cigarette Butt Measurement (mm)
------	--------------------------------	-----------------------	---------------------------------

Section: Used_Butt_Measur 11 of 11

Blank? Y

Section Status: Created

Visit: WEEK 12

Section Date: 29-05-2007

Entered By: Sharon Ladenes

Entry Time: 05-10-2007 13:30:20

Last Modification Time:

Page number: 43

USED STUDY TOBACCO-BURNING CIGARETTE BUTT MEASUREMENT

Date	Scheduled Collection Period	Cigarette Butt Number	Cigarette Butt Measurement (mm)
------	--------------------------------	-----------------------	---------------------------------

CRF Report for Study E6270229



Patient: 2002

CRF: Week 12(3)

Visit: WEEK 12

Entered By: Sharon Ladenes

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CD_001

Blank? Y

Visit Date: 29-05-2007

Entry Time: 05-10-2007 13:30:29

Modification Time:

Approval Time:

Verification Time:

Investigator: RR_001

CRF Page #: 17

Document #: R160352713

CRF Status: Created

Approver:

Verifier:

Section: Unused_Study_Pro	1 of 2	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 29-05-2007	
Entered By: Sharon Ladenes		Entry Time: 05-10-2007 13:30:29	
		Last Modification Time:	
		Page number: 44	
Unused Study Product Returned			
Date	Actual Time	Product Returned	Flavor
			Amount Returned
			Packs Individual Cigarettes / pouches

Section: Study_Prod_Dispe	2 of 2	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 29-05-2007	
Entered By: Sharon Ladenes		Entry Time: 05-10-2007 13:30:29	
		Last Modification Time:	
		Page number: 44	
STUDY PRODUCT DISPENSATION			
Date	Actual Time	Product Dispensed	Flavor
			Amount Dispensed

CRF Report for Study E6270229



Patient: 2002	Site: CD_001	Investigator: RR_001
CRF: Week 14	Blank? Y	CRF Page #: 18
Visit: WEEK 14	Visit Date: 12-06-2007	Document #: R160352813
Entered By: Sharon Ladenes	Entry Time: 05-10-2007 13:30:37	CRF Status: Created
Discrepancies: None	Modification Time:	
Approval Status: Not Approved	Approval Time:	Approver:
Verification: Not Verified	Verification Time:	Verifier:
Comment:		

Section: Hdyf_Oral_Health		1 of 5	Blank? Y	Section Status: Created
Visit: WEEK 14		Section Date: 12-06-2007		
Entered By: Sharon Ladenes		Entry Time: 05-10-2007 13:30:37		
		Last Modification Time:		
		Page number: 45		
HDYF? / ORAL HEALTH QUESTIONS INQUIRY				
Oral Health Questions				
Actual Time	HDYF Performed?	Performed?	Comments	

Section: Expired_Carbon_M		2 of 5	Blank? Y	Section Status: Created
Visit: WEEK 14		Section Date: 12-06-2007		
Entered By: Sharon Ladenes		Entry Time: 05-10-2007 13:30:37		
		Last Modification Time:		
		Page number: 45		
EXPIRED CARBON MONOXIDE				
Actual Time	ECO Level (ppm)	%COHb	Comments	

Section: Vital		3 of 5	Blank? Y	Section Status: Created
Visit: WEEK 14		Section Date: 12-06-2007		
Entered By: Sharon Ladenes		Entry Time: 05-10-2007 13:30:37		
		Last Modification Time:		
		Page number: 45		
VITAL SIGNS				
Actual Time	Blood Pressure	Pulse	Respiratory Rate	Oral Temperature
	Systolic Diastolic			xxx.x
Unit				
Comments				

Section: Unused_Study_Pro		4 of 5	Blank? Y	Section Status: Created
Visit: WEEK 14		Section Date: 12-06-2007		
Entered By: Sharon Ladenes		Entry Time: 05-10-2007 13:30:37		
		Last Modification Time:		

CRF Report for Study E6270229



Patient: 2002

CRF: Week 14

Visit: WEEK 14

Site: CD_001

Blank? Y

Visit Date: 12-06-2007

Investigator: RR_001

CRF Page #: 18

Document #: R160352813

Section: Unused_Study_Pro 4 of 5

Page number: 46

Unused Study Product Returned

Product Returned	Flavor	Amount Returned	
		Packs	Individual Cigarettes / pouches

Section: Study_Prod_Dispe

5 of 5

Blank? Y

Section Status: Created

Visit: WEEK 14

Section Date: 12-06-2007

Entered By: Sharon Ladenes

Entry Time: 05-10-2007 13:30:37

Last Modification Time:

Page number: 46

STUDY PRODUCT DISPENSATION

Actual Time	Product Dispensed	Flavor	Amount Dispensed
-------------	-------------------	--------	------------------

CRF Report for Study E6270229



Patient: 2002	Site: CD_001	Investigator: RR_001
CRF: Week 16	Blank? Y	CRF Page #: 19
Visit: WEEK 16	Visit Date: 26-06-2007	Document #: R160352913
Entered By: Sharon Ladenes	Entry Time: 05-10-2007 13:30:51	CRF Status: Created
Discrepancies: None	Modification Time:	Approver:
Approval Status: Not Approved	Approval Time:	Verifier:
Verification: Not Verified	Verification Time:	
Comment:		

Section: Pro_Questionnaire	1 of 6	Blank? Y	Section Status: Created
Visit: WEEK 16		Section Date: 26-06-2007	
Entered By: Sharon Ladenes		Entry Time: 05-10-2007 13:30:51	
		Last Modification Time:	
		Page number: 47	
PRO QUESTIONNAIRES With the possible exception of urinating, did subject complete Smoker Core Questionnaire PRIOR to any study procedures being performed?			
			YES / NO

Section: Hdyl_Oral_Health	2 of 6	Blank? Y	Section Status: Created
Visit: WEEK 16		Section Date: 26-06-2007	
Entered By: Sharon Ladenes		Entry Time: 05-10-2007 13:30:51	
		Last Modification Time:	
		Page number: 47	
HDYF? / ORAL HEALTH QUESTIONS INQUIRY			
		Oral Health Questions	
Actual Time	HDYF Performed?	Performed?	Comments

Section: Vital	3 of 6	Blank? Y	Section Status: Created
Visit: WEEK 16		Section Date: 26-06-2007	
Entered By: Sharon Ladenes		Entry Time: 05-10-2007 13:30:51	
		Last Modification Time:	
		Page number: 47	
VITAL SIGNS			
Actual Time	Blood Pressure	Pulse	Respiratory Rate
	Systolic Diastolic		Oral Temperature
			xxx.x
Unit			
Comments			

Section: Expired_Carbon_M	4 of 6	Blank? Y	Section Status: Created
Visit: WEEK 16		Section Date: 26-06-2007	

CRF Report for Study E6270229



Patient: 2002

CRF: Week 16

Visit: WEEK 16

Site: CD_001

Blank? Y

Visit Date: 26-06-2007

Investigator: RR_001

CRF Page #: 19

Document #: R160352913

Section: Expired_Carbon_M 4 of 6

Entered By: Sharon Ladenes

Entry Time: 05-10-2007 13:30:51

Last Modification Time:

Page number: 47

EXPIRED CARBON MONOXIDE

Actual Time

ECO Level (ppm)

%COHb

Comments

Section: Unused_Study_Pro 5 of 6

Blank? Y

Section Status: Created

Visit: WEEK 16

Section Date: 26-06-2007

Entered By: Sharon Ladenes

Entry Time: 05-10-2007 13:30:51

Last Modification Time:

Page number: 48

Unused Study Product Returned

Product Returned

Flavor

Amount Returned

Packs

Individual Cigarettes / pouches

Section: Study_Prod_Dispe 6 of 6

Blank? Y

Section Status: Created

Visit: WEEK 16

Section Date: 26-06-2007

Entered By: Sharon Ladenes

Entry Time: 05-10-2007 13:30:51

Last Modification Time:

Page number: 48

STUDY PRODUCT DISPENSATION

Actual Time

Product Dispensed

Flavor

Amount Dispensed

CRF Report for Study E6270229

Patient: 2002	Site: CD_001	Investigator: RR_001
CRF: Week 18	Blank? Y	CRF Page #: 20
Visit: WEEK 18	Visit Date: 10-07-2007	Document #: R148524813
Entered By: Sharon Ladenes	Entry Time: 13-07-2007 10:44:22	CRF Status: Created
Discrepancies: None	Modification Time: 13-07-2007 10:52:34	
Approval Status: Not Approved	Approval Time:	Approver:
Verification: Not Verified	Verification Time:	Verifier:
Comment:		

Section: Hdyf_Oral_Health	1 of 5	Blank? Y	Section Status: Created
Visit: WEEK 18		Section Date: 10-07-2007	
Entered By: Sharon Ladenes		Entry Time: 13-07-2007 10:44:22	
		Last Modification Time: 13-07-2007 10:52:28	
		Page number: 49	
HDYF? / ORAL HEALTH QUESTIONS INQUIRY			
		Oral Health Questions	
Actual Time	HDYF Performed?	Performed?	Comments

Section: Expired_Carbon_M	2 of 5	Blank? Y	Section Status: Created
Visit: WEEK 18		Section Date: 10-07-2007	
Entered By: Sharon Ladenes		Entry Time: 13-07-2007 10:44:22	
		Last Modification Time: 13-07-2007 10:52:28	
		Page number: 49	
EXPIRED CARBON MONOXIDE			
Actual Time	ECO Level (ppm)	%COHb	Comments

Section: Vital	3 of 5	Blank? Y	Section Status: Created
Visit: WEEK 18		Section Date: 10-07-2007	
Entered By: Sharon Ladenes		Entry Time: 13-07-2007 10:44:22	
		Last Modification Time: 13-07-2007 10:52:28	
		Page number: 49	
VITAL SIGNS			
Actual Time	Blood Pressure	Pulse	Respiratory Rate
	Systolic	Diastolic	Oral Temperature
			xxx.x
Unit			
Comments			

Section: Unused_Study_Pro	4 of 5	Blank? Y	Section Status: Created
Visit: WEEK 18		Section Date: 10-07-2007	
Entered By: Sharon Ladenes		Entry Time: 13-07-2007 10:44:22	
		Last Modification Time: 13-07-2007 10:52:28	

CRF Report for Study E6270229



Patient: 2002
CRF: Week 18
Visit: WEEK 18

Site: CD_001
Blank? Y
Visit Date: 10-07-2007

Investigator: RR_001
CRF Page #: 20
Document #: R148524813

Section: Unused_Study_Pro	4 of 5	Page number: 50
Unused Study Product Returned		
Product Returned	Flavor	Amount Returned Packs Individual Cigarettes / pouches

Section: Study_Prod_Dispe	5 of 5	Blank? Y	Section Status: Created
Visit: WEEK 18		Section Date: 10-07-2007	
Entered By: Sharon Ladenes		Entry Time: 13-07-2007 10:44:22	
		Last Modification Time: 13-07-2007 10:52:28	
		Page number: 50	
STUDY PRODUCT DISPENSATION			
Actual Time	Product Dispensed	Flavor	Amount Dispensed

CRF Report for Study E6270229



Patient: 2002	Site: CD_001	Investigator: RR_001
CRF: Week 20	Blank? Y	CRF Page #: 21
Visit: WEEK 20	Visit Date: 24-07-2007	Document #: R160353113
Entered By: Sharon Ladenes	Entry Time: 05-10-2007 13:31:28	CRF Status: Created
Discrepancies: None	Modification Time:	Approver:
Approval Status: Not Approved	Approval Time:	Verifier:
Verification: Not Verified	Verification Time:	
Comment:		

Section: Pro_Questionnair Visit: WEEK 20 Entered By: Sharon Ladenes	1 of 6	Blank? Y	Section Date: 24-07-2007 Entry Time: 05-10-2007 13:31:28 Last Modification Time: Page number: 51	Section Status: Created
PRO QUESTIONNAIRES				
With the possible exception of urinating, did subject complete Smoker Core Questionnaire PRIOR to any study procedures being performed?				YES / NO

Section: Hdyf_Oral_Health Visit: WEEK 20 Entered By: Sharon Ladenes	2 of 6	Blank? Y	Section Date: 24-07-2007 Entry Time: 05-10-2007 13:31:28 Last Modification Time: Page number: 51	Section Status: Created
HDYF? / ORAL HEALTH QUESTIONS INQUIRY				
Oral Health Questions				
Actual Time	HDYF Performed?	Performed?	Comments	

Section: Vital Visit: WEEK 20 Entered By: Sharon Ladenes	3 of 6	Blank? Y	Section Date: 24-07-2007 Entry Time: 05-10-2007 13:31:28 Last Modification Time: Page number: 51	Section Status: Created	
VITAL SIGNS					
Actual Time	Blood Pressure Systolic Diastolic	Pulse	Respiratory Rate	Oral Temperature xxx.x	Unit
Comments					

Section: Expired_Carbon_M Visit: WEEK 20	4 of 6	Blank? Y	Section Date: 24-07-2007	Section Status: Created
---	--------	----------	--------------------------	-------------------------

CRF Report for Study E6270229



Patient: 2002
CRF: Week 20
Visit: WEEK 20

Site: CD_001
Blank? Y
Visit Date: 24-07-2007

Investigator: RR_001
CRF Page #: 21
Document #: R160353113

Section: Expired_Carbon_M 4 of 6

Entered By: Sharon Ladenes

Entry Time: 05-10-2007 13:31:28

Last Modification Time:

Page number: 51

EXPIRED CARBON MONOXIDE

Actual Time	ECO Level (ppm)	%COHb	Comments
-------------	-----------------	-------	----------

Section: Unused_Study_Pro 5 of 6

Blank? Y

Section Status: Created

Visit: WEEK 20

Section Date: 24-07-2007

Entered By: Sharon Ladenes

Entry Time: 05-10-2007 13:31:28

Last Modification Time:

Page number: 52

Unused Study Product Returned

Product Returned	Flavor	Amount Returned	
		Packs	Individual Cigarettes / pouches

Section: Study_Prod_Dispe 6 of 6

Blank? Y

Section Status: Created

Visit: WEEK 20

Section Date: 24-07-2007

Entered By: Sharon Ladenes

Entry Time: 05-10-2007 13:31:28

Last Modification Time:

Page number: 52

STUDY PRODUCT DISPENSATION

Actual Time	Product Dispensed	Flavor	Amount Dispensed
-------------	-------------------	--------	------------------

CRF Report for Study E6270229



Patient: 2002	Site: CD_001	Investigator: RR_001
CRF: Week 22	Blank? Y	CRF Page #: 22
Visit: WEEK 22	Visit Date: 07-08-2007	Document #: R160353213
Entered By: Sharon Ladenes	Entry Time: 05-10-2007 13:31:39	CRF Status: Created
Discrepancies: None	Modification Time:	Approver:
Approval Status: Not Approved	Approval Time:	Verifier:
Verification: Not Verified	Verification Time:	
Comment:		

Section: Hdyf_Oral_Health	1 of 5	Blank? Y	Section Status: Created
Visit: WEEK 22		Section Date: 07-08-2007	
Entered By: Sharon Ladenes		Entry Time: 05-10-2007 13:31:39	
		Last Modification Time:	
		Page number: 53	
HDYF? / ORAL HEALTH QUESTIONS INQUIRY			
		Oral Health	
		Questions	
Actual Time	HDYF Performed?	Performed?	Comments

Section: Expired_Carbon_M	2 of 5	Blank? Y	Section Status: Created
Visit: WEEK 22		Section Date: 07-08-2007	
Entered By: Sharon Ladenes		Entry Time: 05-10-2007 13:31:39	
		Last Modification Time:	
		Page number: 53	
EXPIRED CARBON MONOXIDE			
Actual Time	ECO Level (ppm)	%COHb	Comments

Section: Vital	3 of 5	Blank? Y	Section Status: Created
Visit: WEEK 22		Section Date: 07-08-2007	
Entered By: Sharon Ladenes		Entry Time: 05-10-2007 13:31:39	
		Last Modification Time:	
		Page number: 53	
VITAL SIGNS			
Actual Time	Blood Pressure		Oral
	Systolic	Diastolic	Temperature
		Pulse	xxx.x
		Respiratory Rate	Unit
Comments			

Section: Unused_Study_Pro	4 of 5	Blank? Y	Section Status: Created
Visit: WEEK 22		Section Date: 07-08-2007	
Entered By: Sharon Ladenes		Entry Time: 05-10-2007 13:31:39	
		Last Modification Time:	

CRF Report for Study E6270229



Patient: 2002

CRF: Week 22

Visit: WEEK 22

Site: CD_001

Blank? Y

Visit Date: 07-08-2007

Investigator: RR_001

CRF Page #: 22

Document #: R160353213

Section: Unused_Study_Pro 4 of 5

Page number: 54

Unused Study Product Returned

Product Returned	Flavor	Amount Returned	
		Packs	Individual Cigarettes / pouches

Section: Study_Prod_Dispe 5 of 5

Blank? Y

Section Status: Created

Visit: WEEK 22

Section Date: 07-08-2007

Entered By: Sharon Ladenes

Entry Time: 05-10-2007 13:31:39

Last Modification Time:

Page number: 54

STUDY PRODUCT DISPENSATION

Actual Time	Product Dispensed	Flavor	Amount Dispensed
-------------	-------------------	--------	------------------

CRF Report for Study E6270229



Patient: 2002	Site: CD_001	Investigator: RR_001
CRF: Week 24 (Eos)	Blank? Y	CRF Page #: 23
Visit: WEEK 24 (EOS)	Visit Date: 21-08-2007	Document #: R160353313
Entered By: Sharon Ladenes	Entry Time: 05-10-2007 13:31:51	CRF Status: Created
Discrepancies: None	Modification Time:	Approver:
Approval Status: Not Approved	Approval Time:	Verifier:
Verification: Not Verified	Verification Time:	
Comment:		

Section: Pro_Questionnair	1 of 12	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)		Section Date: 21-08-2007	
Entered By: Sharon Ladenes		Entry Time: 05-10-2007 13:31:51	
		Last Modification Time:	
		Page number: 55	
PRO QUESTIONNAIRES			
Date	1. With the possible exception of urinating, did subject complete Smoker Routine Questionnaire PRIOR to any study procedures being performed?	YES / NO	

Section: Urine_Drug	2 of 12	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)		Section Date: 21-08-2007	
Entered By: Sharon Ladenes		Entry Time: 05-10-2007 13:31:51	
		Last Modification Time:	
		Page number: 55	
Drug Screen			
Date	Drug Screen Result		

Section: Alcohol_Screen	3 of 12	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)		Section Date: 21-08-2007	
Entered By: Sharon Ladenes		Entry Time: 05-10-2007 13:31:51	
		Last Modification Time:	
		Page number: 55	
Alcohol Screen			
Date	Breathalyzer Result		

Section: Preg_Test	4 of 12	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)		Section Date: 21-08-2007	
Entered By: Sharon Ladenes		Entry Time: 05-10-2007 13:31:51	
		Last Modification Time:	
		Page number: 55	
Pregnancy Test			

CRF Report for Study E6270229



Patient: 2002

CRF: Week 24 (Eos)

Visit: WEEK 24 (EOS)

Site: CD_001

Blank? Y

Visit Date: 21-08-2007

Investigator: RR_001

CRF Page #: 23

Document #: R160353313

Section: Preg_Test	4 of 12
Date	Result

Section: Urine_Coll	5 of 12	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)	Section Date: 21-08-2007	Entry Time: 05-10-2007 13:31:51	
Entered By: Sharon Ladenes	Last Modification Time:	Page number: 55	
24-Hour Urine Collection			
Scheduled Timepoint	Start Date	Start Time	Stop Date
		Stop Time	Total Volume
			Comments

Section: ECG	6 of 12	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)	Section Date: 21-08-2007	Entry Time: 05-10-2007 13:31:51	
Entered By: Sharon Ladenes	Last Modification Time:	Page number: 56	
12-LEAD ELECTROCARDIOGRAM REPORT			
Actual Time	Ventricular Heart Rate		
	Cardiac Cycle Measurements		
PR Interval	QRS Duration	QT Interval	QTc Interval
ECG INTERPRETATION:			
Comments (related to abnormal, CS findings only):			

Section: Hdyl_Oral_Health	7 of 12	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)	Section Date: 21-08-2007	Entry Time: 05-10-2007 13:31:51	
Entered By: Sharon Ladenes	Last Modification Time:	Page number: 57	
HDYF? / ORAL HEALTH QUESTIONS INQUIRY			
Date	Actual Time	HDYF Performed?	Oral Health Questions Performed?
			Comments

Section: Vital	8 of 12	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)	Section Date: 21-08-2007	Entry Time: 05-10-2007 13:31:51	
Entered By: Sharon Ladenes	Last Modification Time:		

CRF Report for Study E6270229



Patient: 2002
CRF: Week 24 (Eos)
Visit: WEEK 24 (EOS)

Site: CD_001
Blank? Y
Visit Date: 21-08-2007

Investigator: RR_001
CRF Page #: 23
Document #: R160353313

Section: Vital		8 of 12		Page number: 57			
VITAL SIGNS							
		Blood Pressure				Oral	
Date	Actual Time	Systolic	Diastolic	Pulse	Respiratory Rate	Temperature xxx.x	Unit
Comments							

Section: Oral_Health_Exam		9 of 12		Blank? Y		Section Status: Created	
Visit: WEEK 24 (EOS)		Section Date: 21-08-2007		Entry Time: 05-10-2007 13:31:51			
Entered By: Sharon Ladenes		Last Modification Time:		Page number: 57			
ORAL HEALTH EXAMINATION							
Date	Procedure			Relevant Findings?*		Findings	

Section: Phys_Exam		10 of 12		Blank? Y		Section Status: Created	
Visit: WEEK 24 (EOS)		Section Date: 21-08-2007		Entry Time: 05-10-2007 13:31:51			
Entered By: Sharon Ladenes		Last Modification Time:		Page number: 58			
PHYSICAL EXAMINATION							
Date	Code Number	Code	Relevant Findings?			Findings	

Section: Weight_Height		11 of 12		Blank? Y		Section Status: Created	
Visit: WEEK 24 (EOS)		Section Date: 21-08-2007		Entry Time: 05-10-2007 13:31:51			
Entered By: Sharon Ladenes		Last Modification Time:		Page number: 58			
WEIGHT & HEIGHT							
Date	Weight xxx.x	Unit	Height xxx.x	Unit			

Section: Lab_Eval		12 of 12		Blank? Y		Section Status: Created	
Visit: WEEK 24 (EOS)		Section Date: 21-08-2007		Entry Time: 05-10-2007 13:31:51			
Entered By: Sharon Ladenes							

CRF Report for Study E6270229

Patient: 2002

Site: CD_001

Investigator: RR_001

CRF: Week 24 (Eos)

Blank? Y

CRF Page #: 23

Visit: WEEK 24 (EOS)

Visit Date: 21-08-2007

Document #: R160353313

Section: Lab_Eval

12 of 12

Last Modification Time:

Page number: 59

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

No, specify

Requisition Number 1

Requisition Number 2 (if applicable)

Were there any clinically significant labs?

(Yes, specify below)

Requisition Number

Test Name

H/L

Lab ID

Lab Name

CRF Report for Study E6270229

Patient: 2002
 CRF: Week 24-2 (Eos)
 Visit: WEEK 24 (EOS)
 Entered By: Sharon Ladenes
 Discrepancies: None
 Approval Status: Not Approved
 Verification: Not Verified
 Comment:

Site: CD_001
 Blank? Y
 Visit Date: 21-08-2007
 Entry Time: 05-10-2007 13:32:04
 Modification Time:
 Approval Time:
 Verification Time:

Investigator: RR_001
 CRF Page #: 24
 Document #: R160353413
 CRF Status: Created
 Approver:
 Verifier:

Section: Pk_Blood_Biomark	1 of 11	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)		Section Date: 21-08-2007	
Entered By: Sharon Ladenes		Entry Time: 05-10-2007 13:32:04	
		Last Modification Time:	
		Page number: 59	
Blood Sampling For Biomarkers/Chemistry/Hematology (following an overnight fast)			
Date	Actual Time	Comments	

Section: Expired_Carbon_M	2 of 11	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)		Section Date: 21-08-2007	
Entered By: Sharon Ladenes		Entry Time: 05-10-2007 13:32:04	
		Last Modification Time:	
		Page number: 59	
EXPIRED CARBON MONOXIDE			
Date	Actual Time	ECO Level (ppm)	%COHb
Comments			

Section: Blood_Sampl_Cohb	3 of 11	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)		Section Date: 21-08-2007	
Entered By: Sharon Ladenes		Entry Time: 05-10-2007 13:32:04	
		Last Modification Time:	
		Page number: 59	
Blood Sampling for %COHb			
Date	Actual Time	Comments	

Section: Pre_Bronch_Spir	4 of 11	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)		Section Date: 21-08-2007	
Entered By: Sharon Ladenes		Entry Time: 05-10-2007 13:32:04	
		Last Modification Time:	
		Page number: 60	
PRE-BRONCHODILATOR BEST BASELINE SPIROMETRY TEST RESULT			
Date	Actual Time		

CRF Report for Study E6270229

Patient: 2002

CRF: Week 24-2 (Eos)

Visit: WEEK 24 (EOS)

Site: CD_001

Blank? Y

Visit Date: 21-08-2007

Investigator: RR_001

CRF Page #: 24

Document #: R160353413

Section: Pre_Bronch_Spir	4 of 11						
Date	of FEV1/FVC Test	Testing Position	FEV1 L	FEV1 Predicted (%)	FVC L	FVC Predicted (%)	Comments

Section: Proventil_Admin	5 of 11	Blank? Y	Section Date: 21-08-2007	Section Status: Created
Visit: WEEK 24 (EOS)		Entry Time: 05-10-2007 13:32:04		
Entered By: Sharon Ladenes		Last Modification Time:		
		Page number: 60		
PROVENTIL ADMINISTRATION				
Date	Actual Time of Proventil Administration	Amount Administered		Comments

Section: Post_Bronch_Spir	6 of 11	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)		Section Date: 21-08-2007	
Entered By: Sharon Ladenes		Entry Time: 05-10-2007 13:32:04	
		Last Modification Time:	
		Page number: 60	
POST-BRONCHODILATOR BEST SPIROMETRY TEST RESULT			
	Actual Time of FEV1/FVC	Testing Position	
Date	Test	FEV1 L	FEV1 Predicted (%)
		FVC L	FVC Predicted (%)
			Comments

Section: Used_Study_Tobac	7 of 11	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)		Section Date: 21-08-2007	
Entered By: Sharon Ladenes		Entry Time: 05-10-2007 13:32:04	
		Last Modification Time:	
		Page number: 61	
USED STUDY TOBACCO-HEATING CIGARETTE COLLECTION			
Scheduled Collection		Number of Study	
Timepoint	Start Date	Tobacco-Heating	Weight of
	Start Time	Cigarettes	Cigarettes Collected
	Stop Date	Collected	(g)
	Stop Time		Any Product
			Deviation?
			If yes, # of other
			Brand
			Comments

Section: Used_Study_Snus	8 of 11	Blank? Y	Section Date: 21-08-2007	Section Status: Created
Visit: WEEK 24 (EOS)		Entry Time: 05-10-2007 13:32:04		
Entered By: Sharon Ladenes				

CRF Report for Study E6270229

Patient: 2002
CRF: Week 24-2 (Eos)
Visit: WEEK 24 (EOS)

Site: CD_001
Blank? Y
Visit Date: 21-08-2007

Investigator: RR_001
CRF Page #: 24
Document #: R160353413

Section: Used_Study_Snus 8 of 11

Last Modification Time:
Page number: 62

USED STUDY SNUS COLLECTION

Scheduled Collection Timepoint	Start Date	Start Time	Stop Date	Stop Time	Number of Study Pouches Collected	Any Product Deviation?	If Yes, # of other brand:	Comments
-----------------------------------	------------	------------	-----------	-----------	--------------------------------------	---------------------------	------------------------------	----------

Section: Used_Study_Burn 9 of 11

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 21-08-2007

Entered By: Sharon Ladenes

Entry Time: 05-10-2007 13:32:04

Last Modification Time:

Page number: 63

USED STUDY TOBACCO-BURNING CIGARETTE COLLECTION

Scheduled Collection Timepoint	Start Date	Start Time	Stop Date	Stop Time	Number of Study Tobacco- Burning Cigarettes Collected	Any Product Deviation?	If Yes, # of other brand:	Comments
-----------------------------------	------------	------------	-----------	-----------	---	---------------------------	------------------------------	----------

Section: Used_Butt_Measur 10 of 11

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 21-08-2007

Entered By: Sharon Ladenes

Entry Time: 05-10-2007 13:32:04

Last Modification Time:

Page number: 64

USUAL STUDY TOBACCO-BURNING CIGARETTE BUTT MEASUREMENT

Date	Scheduled Collection Period	Cigarette Butt Number	Cigarette Butt Measurement (mm)
------	--------------------------------	-----------------------	---------------------------------

Section: Used_Butt_Measur 11 of 11

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 21-08-2007

Entered By: Sharon Ladenes

Entry Time: 05-10-2007 13:32:04

Last Modification Time:

Page number: 65

USED STUDY TOBACCO-BURNING CIGARETTE BUTT MEASUREMENT

Date	Scheduled Collection Period	Cigarette Butt Number	Cigarette Butt Measurement (mm)
------	--------------------------------	-----------------------	---------------------------------

CRF Report for Study E6270229



Patient: 2002	Site: CD_001	Investigator: RR_001
CRF: Week 24-3	Blank? Y	CRF Page #: 25
Visit: WEEK 24 (EOS)	Visit Date: 21-08-2007	Document #: R160353513
Entered By: Sharon Ladenes	Entry Time: 05-10-2007 13:32:13	CRF Status: Created
Discrepancies: None	Modification Time:	Approver:
Approval Status: Not Approved	Approval Time:	Verifier:
Verification: Not Verified	Verification Time:	
Comment:		

Section: Unused_Study_Pro	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)	Section Date: 21-08-2007	
Entered By: Sharon Ladenes	Entry Time: 05-10-2007 13:32:13	
	Last Modification Time:	
	Page number: 65A	

Unused Study Product Returned				Amount Returned	
Date	Actual Time	Product Returned	Flavor	Packs	Individual Cigarettes / pouches

CRF Report for Study E6270229

Patient: 2002
CRF: Precon_Med
Visit: PRECON_MEDS
Entered By: Sharon Ladenes
Discrepancies: None
Approval Status: Not Approved
Verification: Not Verified
Comment:

Site: CD_001
Blank? N
Visit Date: 06-02-2007
Entry Time: 13-09-2007 12:23:44
Modification Time: 07-01-2008 15:46:26
Approval Time:
Verification Time:

Investigator: RR_001
CRF Page #: 26
Document #: R156482313
CRF Status: Entry Complete
Approver:
Verifier:

Section: Pre_Conmed		Blank? N		Section Status: Entry Complete					
Visit: PRECON_MEDS		Section Date: 06-02-2007							
Entered By: Sharon Ladenes		Entry Time: 13-09-2007 12:23:44							
		Last Modification Time: 07-01-2008 15:46:26							
		Page number: 66							
Previous and Concomitant Medications									
Has the subject taken any medications prior to the first use of study product and/or during the study as restricted by the protocol?									
YES									
Seq #	Drug Name	Indication	Dose / Dose Unit	Route	Specify	Freq	Specify	Start Date	Stop Date/Ongoing
1	EXEDRIN MIGRAINE	HEADACHE	2 TABS	PO		PRN		00-00-1997	ONGOING

CRF Report for Study E6270229

Patient: 2002
CRF: AE
Visit: AE
Entered By: Sharon Ladenes
Discrepancies: None
Approval Status: Not Approved
Verification: Not Verified
Comment:

Site: CD_001
Blank? N
Visit Date: 22-08-2007
Entry Time: 13-09-2007 12:26:11
Modification Time: 13-09-2007 12:26:39
Approval Time:
Verification Time:

Investigator: RR_001
CRF Page #: 27
Document #: R156483113
CRF Status: Entry Complete

Approver:
Verifier:

Section: Ae_Med		Blank? N		Section Status: Entry Complete					
Visit: AE		Section Date: 22-08-2007							
Entered By: Sharon Ladenes		Entry Time: 13-09-2007 12:26:11							
		Last Modification Time: 13-09-2007 12:26:39							
		Page number: 67							

Adverse Events											
Did the subject experience any adverse events? NO											
Event No.	Adverse Event	Date	Onset Time	Resolved/Changed Date	Time	Serious Event?	Severity	Relationship to Product	Relationship to Procedure	Action Taken	Outcome to Date

CRF Report for Study E6270229



Patient: 2002
CRF: Ecg_Unscheduled
Visit: ECG_UNSCHEDED
Entered By: Sharon Ladenaes
Discrepancies: None
Approval Status: Not Approved
Verification: Not Verified
Comment:

Site: CD_001
Blank? Y
Visit Date: 00-00-
Entry Time: 12-09-2007 18:48:03
Modification Time:
Approval Time:
Verification Time:

Investigator: RR_001
CRF Page #: 28
Document #: R156333913
CRF Status: Created

Approver:
Verifier:

Section: ECG		Blank? Y		Section Status: Created				
Visit: ECG_UNSCHEDED		Section Date: 00-00-						
Entered By: Sharon Ladenaes		Entry Time: 12-09-2007 18:48:03						
		Last Modification Time:						
		Page number: 68						
UNSCHEDULED 12-LEAD ELECTROCARDIOGRAM REPORT								
		Ventricular		Cardiac Cycle Measurements				
Date	Actual Time	Heart Rate	PR Interval	QRS Duration	QT Interval	QTc Interval	Interpretation	Comments

CRF Report for Study E6270229

Patient: 2002

CRF: Lab_Unscheduled

Visit: LAB_UNSCHE

Entered By: Sharon Ladena

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CD_001

Blank? Y

Visit Date: 00-00-

Entry Time: 12-09-2007 18:47:37

Modification Time:

Approval Time:

Verification Time:

Investigator: RR_001

CRF Page #: 29

Document #: R156333613

CRF Status: Created

Approver:

Verifier:

Section: Lab_Eval

Visit: LAB_UNSCHE

Entered By: Sharon Ladena

Blank? Y

Section Date: 00-00-

Entry Time: 12-09-2007 18:47:37

Last Modification Time:

Page number: 69

Section Status: Created

Unscheduled Laboratory Evaluations

Date	Requisition Number	Clinically Significant?	Test Name	High(H)/Low(L)	If Clinically Significant, Specify Lab ID	Lab Name	Comments
------	--------------------	----------------------------	-----------	----------------	--	----------	----------

CRF Report for Study E6270229

Patient: 2002

CRF: Vital_Unscheduled

Visit: VITAL_UNSCHE

Entered By: Sharon Ladenes

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CD_001

Blank? Y

Visit Date: 00-00-

Entry Time: 12-09-2007 18:47:17

Modification Time:

Approval Time:

Verification Time:

Investigator: RR_001

CRF Page #: 30

Document #: R156333413

CRF Status: Created

Approver:

Verifier:

Section: Vital

Visit: VITAL_UNSCHE

Entered By: Sharon Ladenes

Blank? Y

Section Date: 00-00-

Entry Time: 12-09-2007 18:47:17

Last Modification Time:

Page number: 70

Section Status: Created

UNSCHEDULED VITAL SIGNS

Date	Actual Time	Blood Pressure		Pulse	Respiratory	Oral	Unit	Comments
		Systolic	Diastolic		Rate	Temperature		
						xxx.x		

CRF Report for Study E6270229

Patient: 2002	Site: CD_001	Investigator: RR_001
CRF: StdY_Prdt_Dis_Unschedule	Blank? Y	CRF Page #: 31
Visit: STDY_PRDT_UNSCHE	Visit Date: 00-00-	Document #: R156333113
Entered By: Sharon Ladenes	Entry Time: 12-09-2007 18:46:43	CRF Status: Created
Discrepancies: None	Modification Time:	Approver:
Approval Status: Not Approved	Approval Time:	Verifier:
Verification: Not Verified	Verification Time:	
Comment:		

Section: Study_Prod_Dispe	Blank? Y	Section Status: Created
Visit: STDY_PRDT_UNSCHE	Section Date: 00-00-	
Entered By: Sharon Ladenes	Entry Time: 12-09-2007 18:46:43	
	Last Modification Time:	
	Page number: 71	

UNSCHEDULED STUDY PRODUCT DISPENSATION

Date	Actual Time	Product Dispensed	Flavor	Amount Dispensed	Comments
------	-------------	-------------------	--------	------------------	----------

CRF Report for Study E6270229

Patient: 2002	Site: CD_001	Investigator: RR_001
CRF: Expired_Co2_Unscheduled	Blank? Y	CRF Page #: 32
Visit: EXPIRED_CO2_UNSC	Visit Date: 00-00-	Document #: R156333013
Entered By: Sharon Ladenes	Entry Time: 12-09-2007 18:46:33	CRF Status: Created
Discrepancies: None	Modification Time:	Approver:
Approval Status: Not Approved	Approval Time:	Verifier:
Verification: Not Verified	Verification Time:	
Comment:		

Section: Expired_Carbon_M	Blank? Y	Section Status: Created
Visit: EXPIRED_CO2_UNSC	Section Date: 00-00-	
Entered By: Sharon Ladenes	Entry Time: 12-09-2007 18:46:33	
	Last Modification Time:	
	Page number: 72	

UNSCHEDULED EXPIRED CARBON MONOXIDE				
Date	Actual Time	ECO Level (ppm)	%COHb	Comments

CRF Report for Study E6270229

Patient: 2002
CRF: Oral_Health_Unscheduled
Visit: ORAL_HEALTH_UNSC
Entered By: Sharon Ladenes
Discrepancies: None
Approval Status: Not Approved
Verification: Not Verified
Comment:

Site: CD_001
Blank? Y
Visit Date: 00-00-
Entry Time: 12-09-2007 18:46:22
Modification Time:
Approval Time:
Verification Time:

Investigator: RR_001
CRF Page #: 33
Document #: R156332913
CRF Status: Created

Approver:
Verifier:

Section: Oral_Health_Exam	Blank? Y	Section Status: Created
Visit: ORAL_HEALTH_UNSC	Section Date: 00-00-	
Entered By: Sharon Ladenes	Entry Time: 12-09-2007 18:46:22	
	Last Modification Time:	
	Page number: 73	

UNSCHEDULED ORAL HEALTH EXAMINATION				
Date	Actual Time	Code	Relevant Findings?	Comment

CRF Report for Study E6270229

Patient: 2002

Site: CD_001

Investigator: RR_001

CRF: Spirometry_Unscheduled

Blank? Y

CRF Page #: 34

Visit: SPIRO_TEST_UNSCH

Visit Date: 00-00-

Document #: R148447313

Entered By: Sharon Ladenes

Entry Time: 12-07-2007 17:54:40

CRF Status: Created

Discrepancies: None

Modification Time: 13-09-2007 16:22:08

Approval Status: Not Approved

Approval Time:

Approver:

Verification: Not Verified

Verification Time:

Verifier:

Comment:

Section: Pre_Bronch_Spir

Blank? Y

Section Status: Created

Visit: SPIRO_TEST_UNSCH

Section Date: 00-00-

Entered By: Sharon Ladenes

Entry Time: 12-07-2007 17:54:40

Last Modification Time: 13-09-2007 16:21:53

Page number: 74

UNSCHEDULED SPIROMETRY TEST RESULT

Date	Actual Time of FEV1/FVC Test	Testing Position	Timepoint based on Proventil Administration	Proventil Administration (and time of Administration)	(Time)	FEV1 L	FEV1 Predicted (%)	FVC L	FVC Predicted (%)	Comments
------	------------------------------------	---------------------	---	--	---------	--------	--------------------------	-------	-------------------------	----------

CRF Report for Study E6270229

Patient: 2002
CRF: Study_Completion
Visit: STUDY_COMP
Entered By: Sharon Ladenes
Discrepancies: Closed
Approval Status: Not Approved
Verification: Not Verified
Comment:

Site: CD_001
Blank? N
Visit Date: 02-04-2007
Entry Time: 21-05-2007 16:13:13
Modification Time: 18-09-2007 09:07:10
Approval Time:
Verification Time:

Investigator: RR_001
CRF Page #: 35
Document #: R142489013
CRF Status: Entry Complete

Approver:
Verifier:

Section: Study_Comp	Blank? N	Section Status: Entry Complete
Visit: STUDY_COMP	Section Date: 02-04-2007	
Entered By: Sharon Ladenes	Entry Time: 21-05-2007 16:13:13	
	Last Modification Time: 12-09-2007 12:43:17	
	Page number: 75	

Study Completion
Did the subject complete the study? NO
Date the subject completed OR withdrew from the study: 02-04-2007
Reason for Withdrawal CONSENT
Specify
Investigator Comments
Principal Investigator
Date 11 Jan 2008

Covance CLS

Marietta Henry, M.D., Director
8211 SciCor Drive - Indianapolis, IN 46214-2985
Tel. +1 (800) 327 7270

LABORATORY REPORT

ACCESSION NO. N526898

Page 1 of 4

INVESTIGATOR: (B17175)

Patricia Chandler, M.D.
c/o Tepan Mehta
Radiant Research Inc
1341 W Mockingbird Ln/Ste 400E
Dallas, TX 75247

PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

SPONSOR REPORT TO:

Russell M. Dixon, MD
Medical Director
Covance CRU, Inc.
3402 Kinsman Boulevard
Madison, WI United States 53704

Screen

COLLECTION TIME: 11:18 DATE: 07-Feb-2007

DATE RECEIVED IN LABORATORY: 08-Feb-2007

DATE REPORTED BY LABORATORY: 08-Feb-2007

SEX: F BIRTHDATE: (b) (6) AGE: 40

SCREENING NUMBER: S2006

Is this Clinically
Significant/ Adverse
Event?

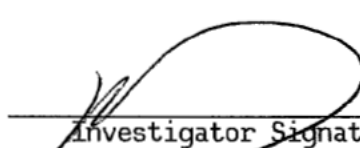
Yes

No

CHEMISTRY PANEL

Total Bili	0.7	0.2-1.2 mg/dL
Alk Phos	67	31-106 U/L
ALT (SGPT)	10	6-34 U/L
AST (SGOT)	12	9-34 U/L
GGT	13	4-49 U/L
LDH	166	53-234 U/L
Urea Nitr	11	4-24 mg/dL
Creatinine	0.8	0.4-1.1 mg/dL
Glucose	81	70-115 mg/dL
Uric Acid	3.2	2.1-7.2 mg/dL
Calcium	9.6	8.3-10.6 mg/dL
Phosphorus	3.0	2.2-5.1 mg/dL
Total Prot	7.4	6.1-8.4 g/dL
Albumin	4.4	3.3-4.9 g/dL
Sodium	138	132-147 mEq/L
Potassium	3.8	3.4-5.4 mEq/L
Chloride	102	94-112 mEq/L

QC'D

See 19 Feb 07
Investigator Signature:16 Feb 2007
Date:

H(High) or L(Low)=Values above or below Covance CLS reference range
T=Telephoned P="Panic" EX=Exclusion-as specified by the sponsor

B17175

(INV)

Covance CLS

Marietta Henry, M.D., Director
8211 SciCor Drive - Indianapolis, IN 46214-2985
Tel. +1 (800) 327 7270

LABORATORY REPORT

ACCESSION NO. N526898

Page 2 of 4

INVESTIGATOR: (B17175)

Patricia Chandler, M.D.
c/o Tepan Mehta
Radiant Research Inc
1341 W Mockingbird Ln/Ste 400E
Dallas, TX 75247

PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

SPONSOR REPORT TO:

Russell M. Dixon, MD
Medical Director
Covance CRU, Inc.
3402 Kinsman Boulevard
Madison, WI United States 53704

Screen

COLLECTION TIME: 11:18 DATE: 07-Feb-2007

DATE RECEIVED IN LABORATORY: 08-Feb-2007

DATE REPORTED BY LABORATORY: 08-Feb-2007

SEX: F BIRTHDATE: (b) (6) AGE: 40

SCREENING NUMBER: S2006

Is this Clinically
Significant/ Adverse
Event?

Yes

No

HEMATOLOGY & DIFFERENTIAL PANEL

HGB	13.9	11.6-16.4 g/dL
HCT	44	34-48 %
RBC	4.6	4.1-5.6 x10 ⁶ /uL
MCV	95	79-98 fL
MCH	30	26-34 pg
MCHC	32	31-38 g/dL
RDW	13.0	12.0-15.0 %
RBC Morph	Normocytic	
WBC	6.19	3.80-10.70 x10 ³ /uL
Neutrophil	4.28	1.96-7.23 x10 ³ /uL
Lymphocyte	1.58	0.91-4.28 x10 ³ /uL
Monocytes	0.24	0.12-0.92 x10 ³ /uL
Eosinophil	0.05	0.00-0.57 x10 ³ /uL
Basophils	0.04	0.00-0.20 x10 ³ /uL
Neutrophil	69.2	40.5-75.0 %
Lymphocyte	25.6	15.4-48.5 %
Monocytes	3.8	2.6-10.1 %
Eosinophil	0.7	0.0-6.8 %
Basophils	0.6	0.0-2.0 %
Platelets	370	140-400 x10 ³ /uL

QC'D

8/19/2007

Investigator Signature:

Date:

H(High) or L(Low)=Values above or below Covance CLS reference range
T=Telephoned P="Panic" EX=Exclusion-as specified by the sponsor

B17175

(INV)

Covance CLS

Marietta Henry, M.D., Director
8211 SciCor Drive - Indianapolis, IN 46214-2985
Tel. +1 (800) 327 7270

LABORATORY REPORT

QC'D

Sur 19/feb/07

ACCESSION NO. N526898

Page 3 of 4

INVESTIGATOR: (B17175)

Patricia Chandler, M.D.
c/o Tepan Mehta
Radiant Research Inc
1341 W Mockingbird Ln/Ste 400E
Dallas, TX 75247

PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

SPONSOR REPORT TO:

Russell M. Dixon, MD
Medical Director
Covance CRU, Inc.
3402 Kinsman Boulevard
Madison, WI United States 53704

Screen

COLLECTION TIME: 11:18 DATE: 07-Feb-2007

DATE RECEIVED IN LABORATORY: 08-Feb-2007

DATE REPORTED BY LABORATORY: 08-Feb-2007

SEX: F BIRTHDATE: (b) (6) AGE: 40

SCREENING NUMBER: S2006

Is this Clinically
Significant/ Adverse
Event?

Yes

No

URINE MACRO & MICRO PANEL

Color	Yellow
Clarity	Hazy
Spec Grav	1.026
pH	5.5
Protein	Trace H
Glucose	Normal
Ketones	Negative
Bilirubin	Negative
Urobilin	Normal
Blood	Trace
Nitrite	+2 H
Leuk Est	Negative
Microscop	Positive

Ref Rng:
Colorless or Yellow
Ref Rng: Clear
1.003-1.035
5.0-8.0
Ref Rng: Negative
Ref Rng: Normal
Ref Rng: Negative
Ref Rng: Negative
Ref Rng: Normal
Ref Rng:
Negative-Trace
Ref Rng: Negative
Ref Rng: Negative

[]

[]

[]

[]

CELLULAR ELEMENTS

RBC	2	0-8 /HPF
WBC	2	0-12 /HPF
Squam Epi	2	0-3 /HPF

CRYSTALS

Ca Ox	Present	Ref Rng: Not present
-------	---------	----------------------

MICROORGANISMS

Bacteria	Present	Ref Rng: Not present
----------	---------	----------------------

Investigator Signature:

H(High) or L(Low)=Values above or below Covance CLS reference range
T-Telephoned P-"Panic" EX-Exclusion-as specified by the sponsor

B17175

(INV)

BUT Repeat
Leak
catch
& send
urine (to S)
next visit
(at 16 Feb 2007)
Date:

Covance CLS

Marietta Henry, M.D., Director
8211 SciCor Drive - Indianapolis, IN 46214-2985
Tel. +1 (800) 327 7270

LABORATORY REPORT

ACCESSION NO. N526898

Page 4 of 4

INVESTIGATOR: (B17175)

Patricia Chandler, M.D.
c/o Tepan Mehta
Radiant Research Inc
1341 W Mockingbird Ln/Ste 400E
Dallas, TX 75247

PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

SPONSOR REPORT TO:

Russell M. Dixon, MD
Medical Director
Covance CRU, Inc.
3402 Kinsman Boulevard
Madison, WI United States 53704

Screen

COLLECTION TIME: 11:18 DATE: 07-Feb-2007

DATE RECEIVED IN LABORATORY: 08-Feb-2007

DATE REPORTED BY LABORATORY: 08-Feb-2007

SEX: F BIRTHDATE: (b) (6) AGE: 40

SCREENING NUMBER: S2006

Is this Clinically
Significant/ Adverse
Event?

Yes

No

MISCELLANEOUS ELEMENTS

Mucous


Present

Ref Rng: Not present

NCS

28 MAR 2007

OCD


Investigator Signature:
Date:

H(High) or L(Low)-Values above or below Covance CLS reference range
T-Telephoned P-"Panic" EX-Exclusion-as specified by the sponsor

B17175

(INV)

Covance CLS

Marietta Henry, M.D., Director
8211 SciCor Drive - Indianapolis, IN 46214-2985
Tel. +1 (800) 327 7270

LABORATORY REPORT

ACCESSION NO. N526898

Page 1 of 1

INVESTIGATOR: (B17175)

Patricia Chandler, M.D.
c/o Tepan Mehta
Radiant Research Inc
1341 W Mockingbird Ln/Ste 400E
Dallas, TX 75247

SPONSOR REPORT TO:

Russell M. Dixon, MD
Medical Director
Covance CRU, Inc.
3402 Kinsman Boulevard
Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME: 11:18 DATE: 07-Feb-2007

DATE RECEIVED IN LABORATORY: 08-Feb-2007

DATE REPORTED BY LABORATORY: 08-Feb-2007

SEX: F BIRTHDATE: (b) (6) AGE: 40

SCREENING NUMBER: S2006

Is this Clinically
Significant/ Adverse
Event?

Yes

No

TOTAL IRON

Total Iron 140 30-160 ug/dL

FOLLICLE STIMULATING HORMONE

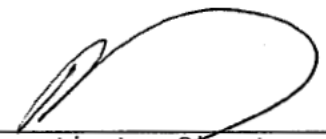
FSH 7.2
Follicular:
4.0-13.0 mIU/mL
Mid-Cycle:
5.0-22.0 mIU/mL
Luteal:
2.0-13.0 mIU/mL
Postmenopausal:
20.0-138.0 mIU/mL

HEPATITIS A ANTIBODY-IGM

HepA IgMab Negative No Ref Rng

sup 19/ Feb 07

0.00


Investigator Signature:

16 Feb 2007
Date:

H(High) or L(Low)-Values above or below Covance CLS reference range
T-Telephoned P-"Panic" EX-Exclusion-as specified by the sponsor

B17175

(INV)

Covance CLS

Marietta Henry, M.D., Director
8211 SciCor Drive - Indianapolis, IN 46214-2985
Tel. +1 (800) 327 7270

LABORATORY REPORT

ACCESSION NO. N526898

Page 1 of 1

INVESTIGATOR: (B17175)

Patricia Chandler, M.D.
c/o Tepan Mehta
Radiant Research Inc
1341 W Mockingbird Ln/Ste 400E
Dallas, TX 75247

SPONSOR REPORT TO:

Russell M. Dixon, MD
Medical Director
Covance CRU, Inc.
3402 Kinsman Boulevard
Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME: 11:18 DATE: 07-Feb-2007

DATE RECEIVED IN LABORATORY: 08-Feb-2007

DATE REPORTED BY LABORATORY: 13-Feb-2007

SEX: F BIRTHDATE: (b) (6) AGE: 40

SCREENING NUMBER: S2006

Is this Clinically
Significant/ Adverse
Event?

Yes

No

HEPATITIS B SURFACE ANTIGEN

HBSAG Negative No Ref Rng

HEPATITIS C VIRUS ANTIBODY

ANTI-HCV Negative No Ref Rng

HEPATITIS B SURFACE ANTIBODY

HBSAB Negative No Ref Rng

ESTRADIOL

Estradiol 95.7 pg/mL
See Inv. Manual

QC'D

Supra/Seb/07

[Signature]
Investigator Signature:

16 Feb 2007
Date:

H(High) or L(Low)=Values above or below Covance CLS reference range
T=Telephoned P="Panic" EX=Exclusion-as specified by the sponsor

B17175

(INV)

Covance CLS

Marietta Henry, M.D., Director
8211 SciCor Drive - Indianapolis, IN 46214-2985
Tel. +1 (800) 327 7270

LABORATORY REPORT

ACCESSION NO. N526898

Page 1 of 1

INVESTIGATOR: (B17175)

Patricia Chandler, M.D.
c/o Tepan Mehta
Radiant Research Inc
1341 W Mockingbird Ln/Ste 400E
Dallas, TX 75247

PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

SPONSOR REPORT TO:

Russell M. Dixon, MD
Medical Director
Covance CRU, Inc.
3402 Kinsman Boulevard
Madison, WI United States 53704

Screen

COLLECTION TIME: 11:18 DATE: 07-Feb-2007

DATE RECEIVED IN LABORATORY: 08-Feb-2007

DATE REPORTED BY LABORATORY: 08-Feb-2007

SEX: F BIRTHDATE: (b) (6) AGE: 40

SCREENING NUMBER: S2006

Is this Clinically
Significant/ Adverse
Event?

Yes

No

HIV 1/HIV 2 ANTIBODY SCREEN


HIV-1/2

Non-Reactive

Reference Range:

Non-Reactive

QC'D

8/19/2007
Investigator Signature:16 Feb 2007
Date:

"This testing is performed as part of a clinical trial. Diagnostic testing shall be conducted locally." H(High) or L(Low)=Values above or below Covance reference range T=Telephoned P="Panic" EX=Exclusions as specified by the Sponsor

B17175

(INV)

Covance CLS

Marietta Henry, M.D., Director
8211 SciCor Drive - Indianapolis, IN 46214-2985
Tel. +1 (800) 327 7270

LABORATORY REPORT

ACCESSION NO. N526898

Page 1 of 1

INVESTIGATOR: (B17175)

Patricia Chandler, M.D.
c/o Tepan Mehta
Radiant Research Inc
1341 W Mockingbird Ln/Ste 400E
Dallas, TX 75247

SPONSOR REPORT TO:

Russell M. Dixon, MD
Medical Director
Covance CRU, Inc.
3402 Kinsman Boulevard
Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME: 11:18 DATE: 07-Feb-2007

DATE RECEIVED IN LABORATORY: 08-Feb-2007

DATE REPORTED BY LABORATORY: 08-Feb-2007

SEX: F BIRTHDATE: (b) (6) AGE: 40

SCREENING NUMBER: S2006

Is this Clinically
Significant/ Adverse
Event?

Yes

No

HEPATITIS B CORE ANTIBODY-IGM

Hep Bc IgM Negative Ref Rng: Negative

QC'D

Suo 19 Feb 07
Investigator Signature:16 Feb 2007
Date:

H(High) or L(Low)=Values above or below Covance CLS reference range
T=Telephoned P="Panic" EX=Exclusion-as specified by the sponsor

B17175

(INV)

LABORATORY REPORT

ACCESSION NO. N526967

Page 1 of 1

INVESTIGATOR: (B17175)

Patricia Chandler, M.D.
c/o Tepan Mehta
Radiant Research Inc
1341 W Mockingbird Ln/Ste 400E
Dallas, TX 75247

SPONSOR REPORT TO:

Russell M. Dixon, MD
Medical Director
Covance CRU, Inc.
3402 Kinsman Boulevard
Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 06:24 DATE: 07-Mar-2007

DATE RECEIVED IN LABORATORY: 08-Mar-2007

DATE REPORTED BY LABORATORY: 19-Mar-2007

SEX: F BIRTHDATE: (b) (6) AGE: 40

SCREENING NUMBER: S2006

Is this Clinically
Significant/ Adverse
Event?

Yes

No

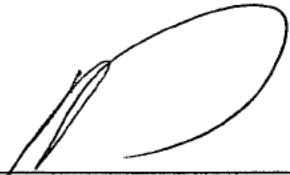
HAS PATIENT FASTED 8 HOURS?

Fasted?

Yes

QC'D

2307 APR 2007


Investigator Signature:


Date:

B17175

(INV)

LABORATORY REPORT

ACCESSION NO. N526967

Page 1 of 3

INVESTIGATOR: (B17175)

Patricia Chandler, M.D.
c/o Tepan Mehta
Radiant Research Inc
1341 W Mockingbird Ln/Ste 400E
Dallas, TX 75247

PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 2

SPONSOR REPORT TO:

Russell M. Dixon, MD
Medical Director
Covance CRU, Inc.
3402 Kinsman Boulevard
Madison, WI United States 53704

Week 0

COLLECTION TIME: 06:24 DATE: 07-Mar-2007

DATE RECEIVED IN LABORATORY: 08-Mar-2007

DATE REPORTED BY LABORATORY: 19-Mar-2007

SEX: F BIRTHDATE: (b) (6) AGE: 40

SCREENING NUMBER: S2006

Is this Clinically
Significant/ Adverse
Event?

Yes

No

CHEMISTRY PANEL

Total Bili	0.5	0.2-1.2 mg/dL
Alk Phos	59	31-106 U/L
ALT (SGPT)	10	6-34 U/L
AST (SGOT)	10	9-34 U/L
GGT	10	4-49 U/L
LDH	136	53-234 U/L
Urea Nitr	10	4-24 mg/dL
Creatinine	0.8	0.4-1.1 mg/dL
Glucose	95	70-115 mg/dL
Uric Acid	2.7	2.1-7.2 mg/dL
Calcium	9.4	8.3-10.6 mg/dL
Phosphorus	4.0	2.2-5.1 mg/dL
Total Prot	6.1	6.1-8.4 g/dL
Albumin	3.6	3.3-4.9 g/dL
Sodium	143	132-147 mEq/L
Potassium	4.4	3.4-5.4 mEq/L
Chloride	109	94-112 mEq/L

QC'D

205 APR 10 2007


Investigator Signature:


Date:

H(High) or L(Low)=Values above or below Covance CLS reference range
T=Telephoned P="Panic" EX=Exclusion-as specified by the sponsor

B17175

(INV)

LABORATORY REPORT

ACCESSION NO. N526967

Page 2 of 3

INVESTIGATOR: (B17175)

Patricia Chandler, M.D.

c/o Tepan Mehta

Radiant Research Inc

1341 W Mockingbird Ln/Ste 400E

Dallas, TX 75247

SPONSOR REPORT TO:

Russell M. Dixon, MD

Medical Director

Covance CRU, Inc.

3402 Kinsman Boulevard

Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 06:24 DATE: 07-Mar-2007

DATE RECEIVED IN LABORATORY: 08-Mar-2007

DATE REPORTED BY LABORATORY: 19-Mar-2007

SEX: F BIRTHDATE: (b) (6) AGE: 40

SCREENING NUMBER: S2006

Is this Clinically
Significant/ Adverse
Event?

Yes

No

HEMATOLOGY& DIFFERENTIAL PANEL

HGB	13.7	11.6-16.4 g/dL
HCT	43	34-48 %
RBC	4.2	4.1-5.6 x10 ⁶ /uL
MCV	102 H	79-98 fL
MCH	33	26-34 pg
MCHC	32	31-38 g/dL
RDW	12.8	12.0-15.0 %
RBC Morph	Macrocytic Anisocytosis	
WBC	6.38	3.80-10.70 x10 ³ /uL
Neutrophil	3.38	1.96-7.23 x10 ³ /uL
Lymphocyte	2.09	0.91-4.28 x10 ³ /uL
Monocytes	0.47	0.12-0.92 x10 ³ /uL
Eosinophil	0.28	0.00-0.57 x10 ³ /uL
Basophils	0.15	0.00-0.20 x10 ³ /uL
Neutrophil	53.1	40.5-75.0 %
Lymphocyte	32.8	15.4-48.5 %
Monocytes	7.4	2.6-10.1 %
Eosinophil	4.4	0.0-6.8 %
Basophils	2.3 H	0.0-2.0 %
Platelets	287	140-400 x10 ³ /uL

QC'D

2007 APR 10 07


Investigator Signature:

23 Mar 2007
Date:

H(High) or L(Low)=Values above or below Covance CLS reference range
T=Telephoned P="Panic" EX=Exclusion-as specified by the sponsor

B17175

(INV)

LABORATORY REPORT

ACCESSION NO. N526967

Page 1 of 1

INVESTIGATOR: (B17175)

Patricia Chandler, M.D.
c/o Tepan Mehta
Radiant Research Inc
1341 W Mockingbird Ln/Ste 400E
Dallas, TX 75247

SPONSOR REPORT TO:

Russell M. Dixon, MD
Medical Director
Covance CRU, Inc.
3402 Kinsman Boulevard
Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 06:24 DATE: 07-Mar-2007

DATE RECEIVED IN LABORATORY: 08-Mar-2007

DATE REPORTED BY LABORATORY: 19-Mar-2007

SEX: F BIRTHDATE: (b) (6) AGE: 40

SCREENING NUMBER: S2006

Is this Clinically
Significant/ Adverse
Event?

Yes

No

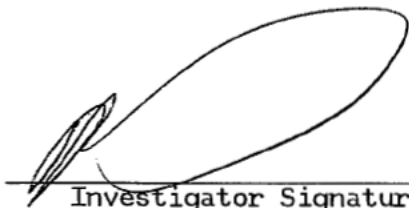
URINE CREATININE, SPOT

Rnd Ur Crt 128


mg/dL No Ref Rng

QC'D

2805 APR 2007



Investigator Signature:



Date:

H(High) or L(Low)=Values above or below Covance CLS reference range
T=Telephoned P="Panic" EX=Exclusion-as specified by the sponsor

B17175

(INV)

LABORATORY REPORT

ACCESSION NO. N526967

Page 1 of 1

INVESTIGATOR: (B17175)
Patricia Chandler, M.D.
c/o Tepan Mehta
Radiant Research Inc
1341 W Mockingbird Ln/Ste 400E
Dallas, TX 75247

SPONSOR REPORT TO:
Russell M. Dixon, MD
Medical Director
Covance CRU, Inc.
3402 Kinsman Boulevard
Madison, WI United States 53704

PROTOCOL 6270-229
INVESTIGATOR NO.: 2
RANDOMIZATION NUMBER:
PATIENT INITIALS: (b) (6)
VISIT: 2

Week 0

COLLECTION TIME: 06:24 DATE: 07-Mar-2007
DATE RECEIVED IN LABORATORY: 08-Mar-2007
DATE REPORTED BY LABORATORY: 19-Mar-2007
SEX: F BIRTHDATE: (b) (6) AGE: 40
SCREENING NUMBER: S2006

Is this Clinically
Significant/ Adverse
Event?

Yes No

TOTAL IRON
Total Iron 122 30-160 ug/dL

C-REACTIVE PROTEIN
CRP-HS <0.020 <=0.287 mg/dL

CARBOXYHEMOGLOBIN
Carboxyhem 2.9 % saturation
No Ref Rng

QC'D

2805 APR 2007

Investigator Signature:

H(High) or L(Low)=Values above or below Covance CLS reference range
T=Telephoned P="Panic" EX=Exclusion-as specified by the sponsor

23 Mar 2007
Date:

B17175

(INV)

LABORATORY REPORT

ACCESSION NO. N526967

Page 1 of 1

INVESTIGATOR: (B18097)
Patricia Chandler, M.D.
c/o Mark Schambura
Radiant Research Inc
1341 W Mockingbird Ln/Ste 400E
Dallas, TX 75247

SPONSOR REPORT TO:
Russell M. Dixon, MD
Medical Director
Covance CRU, Inc.
3402 Kinsman Boulevard
Madison, WI United States 53704

PROTOCOL 6270-229
INVESTIGATOR NO.: 2
RANDOMIZATION NUMBER:
PATIENT INITIALS: (b) (6)
VISIT: 2

Week 0
COLLECTION TIME: 06:24 DATE: 07-Mar-2007
DATE RECEIVED IN LABORATORY: 08-Mar-2007
DATE REPORTED BY LABORATORY: 19-Apr-2007
SEX: F BIRTHDATE: (b) (6) AGE: 40
SCREENING NUMBER: S2006

Is this Clinically
Significant/ Adverse
Event?
Yes No

HOMOCYSTEINE
*1 HCY 9.83 3.36-20.44 umol/L

QC'D

11/29 May 2007

Note #1 - WARNING: Specimens from patients who are on drug therapy involving S-adenosyl-methionine may show falsely elevated levels of homocysteine. Specimens from patients taking methotrexate, carbamazepine, phenytoin, nitrous oxide or 6-azauridine triacetate may have elevated levels of homocysteine due to their effect on the metabolic pathway.

[Signature]
Investigator Signature:

30 APR 2007
Date:

H(High) or L(Low)=Values above or below Covance CLS reference range
T=Telephoned P="Panic" EX=Exclusion-as specified by the sponsor

B18097

(INV)

LABORATORY REPORT

ACCESSION NO. N526967

Page 1 of 1

INVESTIGATOR: (B17175)

Patricia Chandler, M.D.

c/o Tepan Mehta

Radiant Research Inc

1341 W Mockingbird Ln/Ste 400E

Dallas, TX 75247

SPONSOR REPORT TO:

Russell M. Dixon, MD

Medical Director

Covance CRU, Inc.

3402 Kinsman Boulevard

Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 06:24 DATE: 07-Mar-2007

DATE RECEIVED IN LABORATORY: 08-Mar-2007

DATE REPORTED BY LABORATORY: 19-Mar-2007

SEX: F BIRTHDATE: (b) (6)

AGE: 40

SCREENING NUMBER: S2006

Is this Clinically
Significant/ Adverse
Event?

Yes

No

HEMOGLOBIN A1C

Hgb A1c

5.4

Normals:

4.3-6.1%

Stable Diabetics:

4.2-11.2%

QC'D

1805 APR 2007

Investigator Signature:

Date:

H(High) or L(Low)=Values above or below Covance CLS reference range
T=Telephoned P="Panic" EX=Exclusion-as specified by the sponsor

B17175

(INV)

Covance CLS

LABORATORY REPORT

ACCESSION NO. N526967

Page 1 of 1

INVESTIGATOR: (B18097)

Patricia Chandler, M.D.
c/o Mark Schambura
Radiant Research Inc
1341 W Mockingbird Ln/Ste 400E
Dallas, TX 75247

SPONSOR REPORT TO:

Russell M. Dixon, MD
Medical Director
Covance CRU, Inc.
3402 Kinsman Boulevard
Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 06:24 DATE: 07-Mar-2007

DATE RECEIVED IN LABORATORY: 08-Mar-2007

DATE REPORTED BY LABORATORY: 21-Mar-2007

SEX: F BIRTHDATE: (b) (6) AGE: 40

SCREENING NUMBER: S2006

Is this Clinically
Significant/ Adverse
Event?

Yes

No

sICAM-1

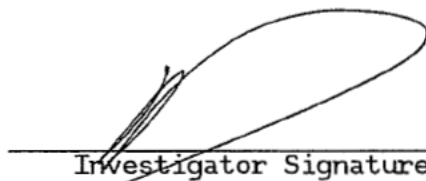
sICAM-1

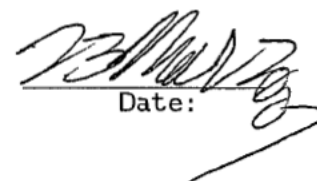
170

115-306 ng/mL

QC'D

205 APR 2007


Investigator Signature:


Date:

H(High) or L(Low)=Values above or below Covance CLS reference range
T=Telephoned P="Panic" EX=Exclusion-as specified by the sponsor

B18097

(INV)

LABORATORY REPORT

ACCESSION NO. N526967

Page 1 of 1

INVESTIGATOR: (B17175)

Patricia Chandler, M.D.
c/o Tepan Mehta
Radiant Research Inc
1341 W Mockingbird Ln/Ste 400E
Dallas, TX 75247

SPONSOR REPORT TO:

Russell M. Dixon, MD
Medical Director
Covance CRU, Inc.
3402 Kinsman Boulevard
Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 06:24 DATE: 07-Mar-2007

DATE RECEIVED IN LABORATORY: 08-Mar-2007

DATE REPORTED BY LABORATORY: 19-Mar-2007

SEX: F BIRTHDATE: (b) (6) AGE: 40

SCREENING NUMBER: S2006

Is this Clinically
Significant/ Adverse
Event?

Yes

No

RBC CELL WASHING (4-ABP-HB) - See Note #1

QC'D

2003 APR 2007

Note #1 - Specimen received beyond stability

Investigator Signature:

H(High) or L(Low)=Values above or below Covance CLS reference range
T=Telephoned P="Panic" EX=Exclusion-as specified by the sponsor

23 Apr 2007
Date:

B17175

(INV)

LABORATORY REPORT

ACCESSION NO. N526967

Page 3 of 3

INVESTIGATOR: (B17175)
Patricia Chandler, M.D.
c/o Tepan Mehta
Radiant Research Inc
1341 W Mockingbird Ln/Ste 400E
Dallas, TX 75247

SPONSOR REPORT TO:
Russell M. Dixon, MD
Medical Director
Covance CRU, Inc.
3402 Kinsman Boulevard
Madison, WI United States 53704

PROTOCOL 6270-229
INVESTIGATOR NO.: 2
RANDOMIZATION NUMBER:
PATIENT INITIALS: (b) (6)
VISIT: 2

Week 0

COLLECTION TIME: 06:24 DATE: 07-Mar-2007
DATE RECEIVED IN LABORATORY: 08-Mar-2007
DATE REPORTED BY LABORATORY: 19-Mar-2007
SEX: F BIRTHDATE: (b) (6) AGE: 40
SCREENING NUMBER: S2006

Is this Clinically
Significant/ Adverse
Event?
Yes No

URINE MACRO & MICRO PANEL

Color Yellow

Clarity Hazy
Spec Grav 1.019
pH 6.0
Protein Negative
Glucose Normal
Ketones Negative
Bilirubin Negative
Urobilin Normal
Blood Negative

Nitrite +2 H
Leuk Est Negative
Microscop

Ref Rng:
Colorless or Yellow
Ref Rng: Clear
1.003-1.035
5.0-8.0
Ref Rng: Negative
Ref Rng: Normal
Ref Rng: Negative
Ref Rng: Negative
Ref Rng: Normal
Ref Rng:
Negative-Trace
Ref Rng: Negative
Ref Rng: Negative
Beyond stability

CELLULAR ELEMENTS - See Note #1

CRYSTALS - See Note #1

MICROORGANISMS - See Note #1

MISCELLANEOUS ELEMENTS - See Note #1

Note #1 - Specimen received beyond stability

Investigator Signature:

H(High) or L(Low)=Values above or below Covance CLS reference range
T=Telephoned P="Panic" EX=Exclusion-as specified by the sponsor

QC'D

B17175

(INV)

205 APR 10 2007

*Pls see
repeat clean
C/S, send
any symptoms
23 Mar 07*