

CRF Report for Study E6270229

Report run by Melissa Zeis at 12-12-2007 15:51:47

Report on Selected Data

Filter: Site CDB_001, Patient 3008

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)

Page ID: D11228813

/ Covance No. 6270-229

Data Clarification Form

To: Covance CRU Daytona Beach
Investigator: Frank Farmer
Date: 16-JAN-2008

Patient#: 3008
Patient Initials:
Reviewer: Dawn Taylor

Form Name / Visit Name	Page # Date	Questions/Comments	Resolution
Vital Signs WEEK 0 (BASELINE) Disc ID: 1236649513 Type: UNIVARIATE	5 21FEB07 Closed: N	Value for Oral Temperature Unit has not been supplied for the W0 assessment. As it appears temp was ND, please confirm unit is to be presented as 'NA'.	<input type="checkbox"/> Temp Unit=NA <input type="checkbox"/> Temp=_____ Unit=_____ <i>Confirmed to be ND</i>

*pm2
012908*

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.

Frank Farmer
Authorized Personnel Signature

23 JAN 2008
Date

CRF Report for Study E6270229



Patient: 3008

CRF: Header_Page

Visit: SCREENING

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? N

Visit Date: 05-02-2007

Entry Time: 10-12-2007 16:04:36

Modification Time: 10-12-2007 16:06:11

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 1

Document #: R169311413

CRF Status: Entry Complete

Approver:

Verifier:

Section: Header_Info

Blank? N

Section Status: Entry Complete

Visit: SCREENING

Section Date: 05-02-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 16:04:36

Last Modification Time: 10-12-2007 16:06:11

Page number: 1

RDC CASE REPORT FORM

SMOKER

Sponsor Name

Investigator

Site

RJ REYNOLDS TOBACCO COMPANY

DR FRANK FARMER

003

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: 3008
 CRF: Screening
 Visit: SCREENING
 Entered By: Melissa Zeis
 Discrepancies: Closed
 Approval Status: Not Approved
 Verification: Not Verified
 Comment:

Site: CDB_001
 Blank? N
 Visit Date: 05-02-2007
 Entry Time: 10-12-2007 16:06:12
 Modification Time: 12-12-2007 10:11:21
 Approval Time:
 Verification Time:

Investigator: CDB_001
 CRF Page #: 2
 Document #: R169311813
 CRF Status: Entry Complete
 Approver:
 Verifier:

Section: Inc_Criteria	1 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 05-02-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 16:06:12	
		Last Modification Time: 10-12-2007 16:13:22	
		Page number: 2	

INCLUSION CRITERIA		
Sequence number	Criteria	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: 05-02-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 16:06:12	
		Last Modification Time: 11-12-2007 11:03:04	
		Page number: 20	

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

CRF Report for Study E6270229

Patient: 3008

CRF: Screening

Visit: SCREENING

Site: CDB_001

Blank? N

Visit Date: 05-02-2007

Investigator: CDB_001

CRF Page #: 2

Document #: R169311813

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: 05-02-2007	Entry Time: 10-12-2007 16:06:12	
Entered By: Melissa Zeis		Last Modification Time: 10-12-2007 16:13:22	Page number: 3	
Exclusion Criteria				Yes/No
Sequence number				
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 Investigator(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 occurred within 30 days prior to Check-in (inclusive).			NO

CRF Report for Study E627022C

Patient: 3008

CRF: Screening

Visit: SCREENING

Site: CDB_001

Blank? N

Visit Date: 05-02-2007

Investigator: CDB_001

CRF Page #: 2

Document #: R169311813

Section: Informed_Consent	4 of 10	Blank? N	Section Date: 05-02-2007	Section Status: Entry Complete
Visit: SCREENING			Entry Time: 10-12-2007 16:06:12	
Entered By: Melissa Zeis			Last Modification Time: 10-12-2007 16:13:22	
		Page number: 4		
Informed Consent				
Date the Subject Signed the Smoker Informed Consent Form 05-02-2007				

Section: Elig	5 of 10	Blank? N	Section Date: 05-02-2007	Section Status: Entry Complete
Visit: SCREENING			Entry Time: 10-12-2007 16:06:12	
Entered By: Melissa Zeis			Last Modification Time: 10-12-2007 16:13:22	
		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 Type	Criteria Number	Deviation	Date Exemption	Granted

Section: Patient_Rep_Outc	6 of 10	Blank? N	Section Date: 05-02-2007	Section Status: Entry Complete
Visit: SCREENING			Entry Time: 10-12-2007 16:06:12	
Entered By: Melissa Zeis			Last Modification Time: 10-12-2007 16:13:22	
		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 Date: 05-02-2007	Section Status: Entry Complete
Visit: SCREENING			Entry Time: 10-12-2007 16:06:12	
Entered By: Melissa Zeis			Last Modification Time: 10-12-2007 16:13:22	
		Page number: 5		
Demographics		Subject Initials		
Date of Birth	Gender	Height	Height Unit	Weight
(b) (6)	F	166.6	CM	95.0
		xxx.x		xxx.x
Ethnicity		Weight Unit KG		

CRF Report for Study E6270229

Patient: 3008

CRF: Screening

Visit: SCREENING

Site: CDB_001

Blank? N

Visit Date: 05-02-2007

Investigator: CDB_001

CRF Page #: 2

Document #: R169311813

Section: Demog		7 of 10	
Hispanic or Latino?	Race	Race other	
UNK	BLACK		

Section: Vital		8 of 10		Blank? N		Section Status: Entry Complete	
Visit: SCREENING		Section Date: 05-02-2007		Entry Time: 10-12-2007 16:06:12		Last Modification Time: 10-12-2007 16:13:22	
Entered By: Melissa Zels		Page number: 5					
VITAL SIGNS							
Blood Pressure		Pulse		Respiratory Rate		Oral Temperature	
Actual Time	Systolic	Diastolic				Unit	
1147	119	71	81	16	36.9	C	
				xxx.x			
Comments							

Section: Hdyf_Oral_Health		9 of 10		Blank? N		Section Status: Entry Complete	
Visit: SCREENING		Section Date: 05-02-2007		Entry Time: 10-12-2007 16:06:12		Last Modification Time: 10-12-2007 16:13:22	
Entered By: Melissa Zeis		Page number: 5					
HDYF? / ORAL HEALTH QUESTIONS INQUIRY							
Actual Time		HDYF Performed?		Oral Health Questions Performed?		Comments	
NR	YES	YES					

Section: Lab_Eval		10 of 10		Blank? N		Section Status: Entry Complete	
Visit: SCREENING		Section Date: 05-02-2007		Entry Time: 10-12-2007 16:06:12		Last Modification Time: 10-12-2007 16:13:22	
Entered By: Melissa Zeis		Page number: 6					
Laboratory Evaluations							
Were the scheduled laboratory samples obtained?				YES		No, specify	
Requisition Number 1		N746118					
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 E627022C

Patient: 3008

CRF: Screening2

Visit: SCREENING

Entered By: Melissa Zeis

Discrepancies: Closed

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? N

Visit Date: 05-02-2007

Entry Time: 10-12-2007 16:14:01

Modification Time: 12-12-2007 10:11:21

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 3

Document #: R169312013

CRF Status: Entry Complete

Approver:

Verifier:

Section: Preg_Test	1 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 05-02-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 16:14:01	
		Last Modification Time: 10-12-2007 16:14:19	
		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: 05-02-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 16:14:01	
		Last Modification Time: 10-12-2007 16:14:19	
		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: 05-02-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 16:14:01	
		Last Modification Time: 10-12-2007 16:14:33	
		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: 05-02-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 16:14:01	
		Last Modification Time: 11-12-2007 11:04:29	
		Page number: 7	

CRF Report for Study E6270229

Patient: 3008

CRF: Screening2

Visit: SCREENING

Site: CDB_001

Blank? N

Visit Date: 05-02-2007

Investigator: CDB_001

CRF Page #: 3

Document #: R169312013

Section: Med_Hx

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Medical History

Does the subject have any relevant medical history?

NO

If so, list the specific diagnosis and/or procedure.

System	Diagnosis/Procedure	Date of Onset	Date of Resolution/Ongoing
SKIN			
EENT			
BREASTS			
RESP			
CARDIO			
LYMPH/HEMA			
GASTRO			
GENITO			
MUSCULO			
ENDOCRINE			
NEURO			
IMMUNO			
PSYCH			
ALLERGIC			
OTHER			

Section: ECG

5 of 10

Blank? N

Section Status: Entry Complete

Visit: SCREENING

Section Date: 05-02-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 16:14:01

Last Modification Time: 10-12-2007 16:43:10

Page number: 8

12-LEAD ELECTROCARDIOGRAM REPORT

Actual Time

Ventricular Heart Rate

1154

68

Cardiac Cycle Measurements

PR Interval

QRS Duration

QT Interval

QTc Interval

150

84

404

418

ECG INTERPRETATION:

NORMAL

Comments (related to abnormal, CS findings only):

Section: Usual_Brand_Cig

6 of 10

Blank? N

Section Status: Entry Complete

Visit: SCREENING

Section Date: 05-02-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 16:14:01

Last Modification Time: 10-12-2007 16:43:10

CRF Report for Study E6270229



Patient: 3008
CRF: Screening2
Visit: SCREENING

Site: CDB_001
Blank? N
Visit Date: 05-02-2007

Investigator: CDB_001
CRF Page #: 3
Document #: R169312013

Section: Usual_Brand_Cig		6 of 10		Page number: 9	
USUAL BRAND CIGARETTE PACK DATA					
Usual Brand	Type	Length			
MISTY	MENTHOL	EXTRA LONG			
		>105MM			
How long have these been the subject's usual brand?					
Style	Pack	UNK	months		
LIGHTS/LOW TAR	HARD	UNK	years		

Section: Ftc_Tar_Level		7 of 10		Blank? N		Section Status: Entry Complete	
Visit: SCREENING		Section Date: 05-02-2007		Entry Time: 10-12-2007 16:14:01			
Entered By: Melissa Zeis		Last Modification Time: 10-12-2007 16:43:10		Page number: 9			
FTC TAR LEVEL OF USUAL BRAND							
FTC Tar Level (mg)							
11.8							

Section: Expired_Carbon_M		8 of 10		Blank? N		Section Status: Entry Complete	
Visit: SCREENING		Section Date: 05-02-2007		Entry Time: 10-12-2007 16:14:01			
Entered By: Melissa Zeis		Last Modification Time: 10-12-2007 16:44:29		Page number: 10			
EXPIRED CARBON MONOXIDE							
Actual Time	ECO Level (ppm)	%COHb	Comments				
1135	10	2.2					

Section: Best_Baseline_Sp		9 of 10		Blank? N		Section Status: Entry Complete	
Visit: SCREENING		Section Date: 05-02-2007		Entry Time: 10-12-2007 16:14:01			
Entered By: Melissa Zeis		Last Modification Time: 10-12-2007 16:44:29		Page number: 10			
BEST BASELINE SPIROMETRY TEST RESULT							
Actual Time	Testing Position	FEV1 L	FEV 1 Predicted (%)	FVC L	FVC Predicted (%)	Comments	
of FEV1/FVC Test							
1200	STANDING	3.01	112	3.39	104		

CRF Report for Study E6270229



Patient: 3008

CRF: Screening2

Visit: SCREENING

Site: CDB_001

Blank? N

Visit Date: 05-02-2007

Investigator: CDB_001

CRF Page #: 3

Document #: R169312013

Section: Irvs_Training	10 of 10	Blank? N	Section Date: 05-02-2007	Entry Time: 10-12-2007 16:14:01	Last Modification Time: 10-12-2007 16:44:29	Page number: 10	Section Status: Entry Complete
Visit: SCREENING							
Entered By: Melissa Zeis							
IVRS TRAINING							
Did Subject receive training on the Daily Call-In Diary (IVRS)?							
YES							

CRF Report for Study E6270229



Patient: 3008

CRF: Week-2

Visit: WEEK -2

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? N

Visit Date: 08-02-2007

Entry Time: 10-12-2007 16:44:36

Modification Time: 10-12-2007 16:45:21

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 4

Document #: R169312413

CRF Status: Entry Complete

Approver:

Verifier:

Section: Usual_Brand_Coll

Blank? N

Section Status: Entry Complete

Visit: WEEK -2

Section Date: 08-02-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 16:44:36

Last Modification Time: 10-12-2007 16:45:21

Page number: 11

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: 3008

CRF: Week 0 Baseline

Visit: WEEK 0 (BASELINE)

Entered By: Melissa Zeis

Discrepancies: Active

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? N

Visit Date: 21-02-2007

Entry Time: 10-12-2007 16:45:22

Modification Time: 11-12-2007 09:46:42

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 5

Document #: R169312513

CRF Status: Entry Complete

Approver:

Verifier:

Section: Pro_Questionnair	1 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 21-02-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 16:45:22	
		Last Modification Time: 10-12-2007 16:59:31	
		Page number: 12A	
PRO QUESTIONNAIRES			
Date	1. With the possible exception of urinating, did subject	YES / NO	
21-02-2007	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: 21-02-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 16:45:22	
		Last Modification Time: 10-12-2007 16:59:31	
		Page number: 12A	
Drug Screen			
Date	Drug Screen Result		
21-02-2007	NEG		

Section: Alcohol_Screen	3 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 21-02-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 16:45:22	
		Last Modification Time: 10-12-2007 16:59:31	
		Page number: 12A	
Alcohol Screen			
Date	Breathalyzer Result		
21-02-2007	NEG		

Section: Preg_Test	4 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 21-02-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 16:45:22	
		Last Modification Time: 10-12-2007 16:59:31	
		Page number: 12A	

CRF Report for Study E6270229

Patient: 3008

CRF: Week 0 Baseline

Visit: WEEK 0 (BASELINE)

Site: CDB_001

Blank? N

Visit Date: 21-02-2007

Investigator: CDB_001

CRF Page #: 5

Document #: R169312513

Section: Preg_Test	4 of 11
Pregnancy Test	
Date	Result
21-02-2007	NEGA TIVE

Section: Urine_Coll	5 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)	Section Date: 21-02-2007		
Entered By: Melissa Zeis	Entry Time: 10-12-2007 16:45:22		
	Last Modification Time: 10-12-2007 16:59:31		
	Page number: 12A		
24-Hour Urine Collection			
Scheduled Timepoint	Start Date	Start Time	Stop Date
SPOT URINE VOID	21-02-2007	1717	NA
0 HOUR TO 24 HOURS	21-02-2007	1717	22-02-2007
			1717
			3530
			Total Volume
			NA
			Comments

Section: Hdyf_Oral_Health	6 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)	Section Date: 21-02-2007		
Entered By: Melissa Zeis	Entry Time: 10-12-2007 16:45:22		
	Last Modification Time: 10-12-2007 16:59:31		
	Page number: 13.1		
HDYF? INQUIRY			
Date	Actual Time	HDYF Performed?	Comments
22-02-2007	0521	YES	

Section: Vital	7 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)	Section Date: 21-02-2007		
Entered By: Melissa Zeis	Entry Time: 10-12-2007 16:45:22		
	Last Modification Time: 10-12-2007 16:59:31		
	Page number: 13.1		
VITAL SIGNS			
		Blood Pressure	Oral
Date	Actual Time	Systolic	Diastolic
21-02-2007	1740	131	79
		Pulse	Respiratory Rate
		83	20
			Temperature
			ND
			xxx.x
Comments			

CRF Report for Study E6270229

Patient: 3008

Site: CDB_001

Investigator: CDB_001

CRF: Week 0 Baseline

Blank? N

CRF Page #: 5

Visit: WEEK 0 (BASELINE)

Visit Date: 21-02-2007

Document #: R169312513

Section: Oral_Health_Exam 8 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 21-02-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 16:45:22

Last Modification Time: 10-12-2007 16:59:31

Page number: 13.1

ORAL HEALTH EXAMINATION

Date

22-02-2007

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

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 21-02-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 16:45:22

Last Modification Time: 10-12-2007 16:59:31

Page number: 14.1

PHYSICAL EXAMINATION

Date

22-02-2007

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

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 21-02-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 16:45:22

Last Modification Time: 10-12-2007 16:59:31

Page number: 14.1

CRF Report for Study E6270229

Patient: 3008

CRF: Week 0 Baseline

Visit: WEEK 0 (BASELINE)

Site: CDB_001

Blank? N

Visit Date: 21-02-2007

Investigator: CDB_001

CRF Page #: 5

Document #: R169312513

Section: Weight_Height		10 of 11		
WEIGHT & HEIGHT				
Date	Weight	Unit	Height	Unit
21-02-2007	97.6	KG	ND	
	xxx.x		xxx.x	

Section: Lab_Eval		11 of 11		Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 21-02-2007			
Entered By: Melissa Zeis		Entry Time: 10-12-2007 16:45:22			
		Last Modification Time: 10-12-2007 16:59:31			
		Page number: 15.1			
Laboratory Evaluations					
Date					
21-02-2007					
Were the scheduled laboratory samples obtained?	YES	No, specify			
Requisition Number 1	N528137				
Requisition Number 2 (if applicable)					
Were there any clinically significant labs?	NO	(Yes, specify below)			
22-02-2007					
	YES				
	N527187				
	NO				
Requisition Number	Test Name	H/L	Lab ID	Lab Name	

CRF Report for Study E627022C



Patient: 3008	Site: CDB_001	Investigator: CDB_001
CRF: Week 0 2baseline	Blank? N	CRF Page #: 5.1
Visit: WEEK 0 (BASELINE)	Visit Date: 21-02-2007	Document #: R169312813
Entered By: Melissa Zeis	Entry Time: 10-12-2007 16:59:58	CRF Status: Entry Complete
Discrepancies: None	Modification Time: 10-12-2007 17:09:11	
Approval Status: Not Approved	Approval Time:	Approver:
Verification: Not Verified	Verification Time:	Verifier:
Comment:		

Section: Pk_Blood_Biomark	1 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 21-02-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 16:59:58	
		Last Modification Time: 10-12-2007 17:05:08	
		Page number: 15.1	
Blood Sampling For Biomarkers/Chemistry/Hematology (following an overnight fast)			
Date	Actual Time	Comments	
22-02-2007	0636		

Section: Expired_Carbon_M	2 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 21-02-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 16:59:58	
		Last Modification Time: 10-12-2007 17:01:03	
		Page number: 15.1	
EXPIRED CARBON MONOXIDE			
Date	Actual Time	ECO Level (ppm)	%COHb
22-02-2007	1220	19	3.6

Section: Blood_Sampl_Cohb	3 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 21-02-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 16:59:58	
		Last Modification Time: 10-12-2007 17:05:08	
		Page number: 15.1	
Blood Sampling for %COHb			
Date	Actual Time	Comments	
22-02-2007	1222		

Section: Pre_Bronch_Spir	4 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 21-02-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 16:59:58	
		Last Modification Time: 10-12-2007 17:05:08	
		Page number: 16.1	

CRF Report for Study E6270229

Patient: 3008

CRF: Week 0 2baseline

Visit: WEEK 0 (BASELINE)

Site: CDB_001

Blank? N

Visit Date: 21-02-2007

Investigator: CDB_001

CRF Page #: 5.1

Document #: R169312813

Section: Pre_Bronch_Spir		4 of 11					
PRE-BRONCHODILATOR BEST BASELINE SPIROMETRY TEST RESULT							
Actual Time							
of FEV1/FVC		Testing			FVC		
Date	Test	Position	FEV1 L	FEV1 Predicted (%)	FVC L	Predicted (%)	Comments
22-02-2007	1544	STANDi NG	2.63	98	3.07	92	

Section: Proventil_Admin	5 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 21-02-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 16:59:58	
		Last Modification Time: 10-12-2007 17:05:08	
		Page number: 16.1	
PROVENTIL ADMINISTRATION			
	Actual Time of Proventil		
Date	Administration	Amount Administered	Comments
22-02-2007	1551	2 METERED PUFFS	

Section: Post_Bronch_Spir	6 of 11	Blank? N	Section Status: Entry Complete				
Visit: WEEK 0 (BASELINE)		Section Date: 21-02-2007					
Entered By: Melissa Zeis		Entry Time: 10-12-2007 16:59:58					
		Last Modification Time: 10-12-2007 17:05:08					
		Page number: 16.1					
POST-BRONCHODILATOR BEST SPIROMETRY TEST RESULT							
	Actual Time of FEV1/FVC	Testing					
Date	Test	Position	FEV1 L	FEV1 Predicted (%)	FVC L	FVC Predicted (%)	Comments
22-02-2007	1608	STANDING	2.89	108	3.21	98	

Section: Unused_Usual_Bra	7 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 21-02-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 16:59:58	
		Last Modification Time: 10-12-2007 17:05:08	
		Page number: 17.1	
Unused Usual Brand Cigarette Pack Collection			
			Yes / No
Date	Does Site have 5 unopened packs of subject's usual		
21-02-2007	brand cigarette to ship to CCLS?		YES

CRF Report for Study E6270229

Patient: 3008

CRF: Week 0 2baseline

Visit: WEEK 0 (BASELINE)

Site: CDB_001

Blank? N

Visit Date: 21-02-2007

Investigator: CDB_001

CRF Page #: 5.1

Document #: R169312813

Section: Usual_Brand_Butt		8 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)		Section Date: 21-02-2007		Entry Time: 10-12-2007 16:59:58			
Entered By: Melissa Zeis		Last Modification Time: 10-12-2007 17:08:32		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	20-02- 2007	1720	21-02-2007	1720	16	NO		
24 HOURS IN-HOUSE	21-02- 2007	1750	22-02-2007	1750	18	NO		

Section: Used_Butt_Measur		9 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)		Section Date: 21-02-2007		Entry Time: 10-12-2007 16:59:58			
Entered By: Melissa Zeis		Last Modification Time: 10-12-2007 17:08:32		Page number: 18.1			

USUAL BRAND CIGARETTE BUTT MEASUREMENT				
Date	Scheduled Collection Period		Cigarette Butt Number	Cigarette Butt Measurement (mm)
21-02-2007	24 HOURS PRIOR TO CHECK-IN		1	51
			2	36
			3	41
			4	50
			5	51
			6	48
			7	52
			8	48
			9	48
			10	49
			11	53
			12	53
			13	54
			14	50
			15	54
			16	53

CRF Report for Study E6270229



Patient: 3008

CRF: Week 0 2baseline

Visit: WEEK 0 (BASELINE)

Site: CDB_001

Blank? N

Visit Date: 21-02-2007

Investigator: CDB_001

CRF Page #: 5.1

Document #: R169312813

Section: Used_Butt_Measur 10 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 21-02-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 16:59:58

Last Modification Time: 10-12-2007 17:08:32

Page number: 19.1

USUAL BRAND CIGARETTE BUTT MEASUREMENT

Scheduled Collection

Date

Period

22-02-2007

24 HOURS IN-HOUSE

Cigarette Butt Number

Cigarette Butt Measurement (mm)

1

41

2

52

3

55

4

54

5

51

6

54

7

49

8

51

9

53

10

48

11

50

12

50

13

54

14

52

15

44

16

55

17

53

18

56

Section: Randomization 11 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 21-02-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 16:59:58

Last Modification Time: 10-12-2007 17:09:11

Page number: 20.1

RANDOMIZATION

Date

Actual Time

Randomization Sequence

22-02-2007

1617

GROUP B

CRF Report for Study E6270229

Patient: 3008

CRF: Week 0 3baseline

Visit: WEEK 0 (BASELINE)

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? N

Visit Date: 21-02-2007

Entry Time: 10-12-2007 17:09:16

Modification Time: 10-12-2007 17:11:02

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 5.2

Document #: R169313013

CRF Status: Entry Complete

Approver:

Verifier:

Section: Study_Prod_Dispe

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 21-02-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 17:09:16

Last Modification Time: 10-12-2007 17:11:02

Page number: 23.1

STUDY PRODUCT DISPENSATION

Date	Actual Time	Product Dispensed	Flavor	Amount Dispensed
22-02-2007	1745	SNUS	SPICE	1
22-02-2007	1745	SNUS	FROST	1
22-02-2007	1745	SNUS	ORIGINAL	1

CRF Report for Study E6270229



Patient: 3008

CRF: Intercurrent_III

Visit: INTERCURRENT ILL

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? N

Visit Date: 21-02-2007

Entry Time: 10-12-2007 17:21:04

Modification Time: 10-12-2007 17:21:20

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 7

Document #: R169313213

CRF Status: Entry Complete

Approver:

Verifier:

Section: Ip_Findings

Blank? N

Section Status: Entry Complete

Visit: INTERCURRENT ILL

Section Date: 21-02-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 17:21:04

Last Modification Time: 10-12-2007 17:21:20

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	Relationship to Procedure	Action Taken
----------	-----------------	------	------	------	------	----------	------------------------------	--------------

CRF Report for Study E6270229

Patient: 3008

CRF: Week 1

Visit: WEEK 1

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? Y

Visit Date: 10-12-2007

Entry Time: 10-12-2007 17:21:21

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 8

Document #: R169313313

CRF Status: Created

Approver:

Verifier:

Section: Hdyf_Oral_Health	1 of 5	Blank? Y	Section Status: Created
Visit: WEEK 1		Section Date: 10-12-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:21:21	
		Last Modification Time:	
		Page number: 22	
HDYF? / ORAL HEALTH QUESTIONS INQUIRY			
		Oral Health	
		Questions	
Actual Time	HDYF Performed?	Performed?	Comments

Section: Vital	2 of 5	Blank? Y	Section Status: Created
Visit: WEEK 1		Section Date: 10-12-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:21:21	
		Last Modification Time:	
		Page number: 22	
VITAL SIGNS			
Actual Time	Blood Pressure	Oral	
	Systolic	Diastolic	
	Pulse	Respiratory Rate	
		Temperature	
		xxx.x	
Unit			
Comments			

Section: Expired_Carbon_M	3 of 5	Blank? Y	Section Status: Created
Visit: WEEK 1		Section Date: 10-12-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:21:21	
		Last Modification Time:	
		Page number: 22	
EXPIRED CARBON MONOXIDE			
Actual Time	ECO Level (ppm)	%COHb	Comments

Section: Unused_Study_Pro	4 of 5	Blank? Y	Section Status: Created
Visit: WEEK 1		Section Date: 10-12-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:21:21	
		Last Modification Time:	

CRF Report for Study E6270229



Patient: 3008
CRF: Week 1
Visit: WEEK 1

Site: CDB_001
Blank? Y
Visit Date: 10-12-2007

Investigator: CDB_001
CRF Page #: 8
Document #: R169313313

Section: Unused_Study_Pro 4 of 5

Page number: 23

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 1

Section Date: 10-12-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 17:21:21

Last Modification Time:

Page number: 23

STUDY PRODUCT DISPENSATION

Actual Time	Product Dispensed	Flavor	Amount Dispensed
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CRF Report for Study E6270229

Patient: 3008

CRF: Week 2

Visit: WEEK 2

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? Y

Visit Date: 10-12-2007

Entry Time: 10-12-2007 17:21:42

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 9

Document #: R169313413

CRF Status: Created

Approver:

Verifier:

Section: Hdyf_Oral_Health	1 of 6	Blank? Y	Section Status: Created
Visit: WEEK 2		Section Date: 10-12-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:21:42	
		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: 10-12-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:21:42	
		Last Modification Time:	
		Page number: 24	
VITAL SIGNS			
Actual Time	Blood Pressure	Oral	
	Systolic	Diastolic	
	Pulse	Respiratory Rate	
		Temperature	
		xxx.x	
Unit			
Comments			

Section: Expired_Carbon_M	3 of 6	Blank? Y	Section Status: Created
Visit: WEEK 2		Section Date: 10-12-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:21:42	
		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: 10-12-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:21:42	
		Last Modification Time:	

CRF Report for Study E6270229

Patient: 3008

CRF: Week 2

Visit: WEEK 2

Site: CDB_001

Blank? Y

Visit Date: 10-12-2007

Investigator: CDB_001

CRF Page #: 9

Document #: R169313413

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: 10-12-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 17:21:42

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: 10-12-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 17:21:42

Last Modification Time:

Page number: 25

STUDY PRODUCT DISPENSATION

Actual Time	Product Dispensed	Flavor	Amount Dispensed
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CRF Report for Study E6270229



Patient: 3008

CRF: Week 4

Visit: WEEK 4

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? Y

Visit Date: 10-12-2007

Entry Time: 10-12-2007 17:21:51

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 10

Document #: R169313513

CRF Status: Created

Approver:

Verifier:

Section: Pro_Questionnaire	1 of 6	Blank? Y	Section Status: Created
Visit: WEEK 4		Section Date: 10-12-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:21:51	
		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: 10-12-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:21:51	
		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: 10-12-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:21:51	
		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: 10-12-2007	

CRF Report for Study E6270229

Patient: 3008
CRF: Week 4
Visit: WEEK 4

Site: CDB_001
Blank? Y
Visit Date: 10-12-2007

Investigator: CDB_001
CRF Page #: 10
Document #: R169313513

Section: Expired_Carbon_M 4 of 6

Entered By: Melissa Zeis

Entry Time: 10-12-2007 17:21:51

Last Modification Time:

Page number: 26

EXPIRED CARBON MONOXIDE

Actual Time	ECO Level (ppm)	%COHb	Comments
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Section: Unused_Study_Pro 5 of 6

Blank? Y

Section Status: Created

Visit: WEEK 4

Section Date: 10-12-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 17:21:51

Last Modification Time:

Page number: 27

Unused Study Product Returned

Product Returned	Flavor	Packs	Amount Returned	Individual Cigarettes / pouches
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Section: Study_Prod_Dispe 6 of 6

Blank? Y

Section Status: Created

Visit: WEEK 4

Section Date: 10-12-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 17:21:51

Last Modification Time:

Page number: 27

STUDY PRODUCT DISPENSATION

Actual Time	Product Dispensed	Flavor	Amount Dispensed
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CRF Report for Study E6270229



Patient: 3008

CRF: Week 6

Visit: WEEK 6

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? Y

Visit Date: 10-12-2007

Entry Time: 10-12-2007 17:22:00

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 11

Document #: R169313613

CRF Status: Created

Approver:

Verifier:

Section: Hdyf_Oral_Health	1 of 5	Blank? Y	Section Status: Created	
Visit: WEEK 6		Section Date: 10-12-2007		
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:22:00		
		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: 10-12-2007		
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:22:00		
		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: 10-12-2007			
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:22:00			
		Last Modification Time:			
		Page number: 28			
VITAL SIGNS					
Actual Time	Blood Pressure	Pulse	Respiratory Rate	Oral Temperature	Unit
	Systolic Diastolic			xxx.x	
Comments					

Section: Unused_Study_Pro	4 of 5	Blank? Y	Section Status: Created		
Visit: WEEK 6		Section Date: 10-12-2007			
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:22:00			
		Last Modification Time:			

CRF Report for Study E6270229



Patient: 3008
CRF: Week 6
Visit: WEEK 6

Site: CDB_001
Blank? Y
Visit Date: 10-12-2007

Investigator: CDB_001
CRF Page #: 11
Document #: R169313613

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: 10-12-2007		
Entered By: Melissa Zeis	Entry Time: 10-12-2007 17:22:00		
Last Modification Time:			
Page number: 29			
STUDY PRODUCT DISPENSATION			
Actual Time	Product Dispensed	Flavor	Amount Dispensed

CRF Report for Study E6270229



Patient: 3008

CRF: Week 8

Visit: WEEK 8

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? Y

Visit Date: 10-12-2007

Entry Time: 10-12-2007 17:22:08

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 13

Document #: R169313813

CRF Status: Created

Approver:

Verifier:

Section: Pro_Questionnair	1 of 6	Blank? Y	Section Status: Created
Visit: WEEK 8		Section Date: 10-12-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:22:08	
		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: Hdyf_Oral_Health	2 of 6	Blank? Y	Section Status: Created
Visit: WEEK 8		Section Date: 10-12-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:22:08	
		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: 10-12-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:22:08	
		Last Modification Time:	
		Page number: 30	
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 8		Section Date: 10-12-2007	

CRF Report for Study E6270229



Patient: 3008
CRF: Week 8
Visit: WEEK 8

Site: CDB_001
Blank? Y
Visit Date: 10-12-2007

Investigator: CDB_001
CRF Page #: 13
Document #: R169313813

Section: Expired_Carbon_M 4 of 6

Entered By: Melissa Zeis

Entry Time: 10-12-2007 17:22:08

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: 10-12-2007

Entry Time: 10-12-2007 17:22:08

Entered By: Melissa Zeis

Last Modification Time:

Page number: 31

Unused Study Product Returned

Product Returned	Flavor	Packs	Amount Returned	Individual Cigarettes / pouches
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Section: Study_Prod_Dispe 6 of 6

Blank? Y

Section Status: Created

Visit: WEEK 8

Section Date: 10-12-2007

Entry Time: 10-12-2007 17:22:08

Entered By: Melissa Zeis

Last Modification Time:

Page number: 31

STUDY PRODUCT DISPENSATION

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

CRF Report for Study E6270229

Patient: 3008

CRF: Week 10

Visit: WEEK 10

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? Y

Visit Date: 10-12-2007

Entry Time: 10-12-2007 17:22:17

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 14

Document #: R169314013

CRF Status: Created

Approver:

Verifier:

Section: Hdyf_Oral_Health	1 of 5	Blank? Y	Section Status: Created
Visit: WEEK 10		Section Date: 10-12-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:22:17	
		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: 10-12-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:22:17	
		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: 10-12-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:22:17	
		Last Modification Time:	
		Page number: 32	
VITAL SIGNS			
Actual Time	Blood Pressure Systolic Diastolic	Pulse	Respiratory Rate
			Oral Temperature xxx.x
Unit			
Comments			

Section: Unused_Study_Pro	4 of 5	Blank? Y	Section Status: Created
Visit: WEEK 10		Section Date: 10-12-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:22:17	
		Last Modification Time:	

CRF Report for Study E6270229

Patient: 3008

CRF: Week 10

Visit: WEEK 10

Site: CDB_001

Blank? Y

Visit Date: 10-12-2007

Investigator: CDB_001

CRF Page #: 14

Document #: R169314013

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: 10-12-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 17:22:17

Last Modification Time:

Page number: 33

STUDY PRODUCT DISPENSATION

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

CRF Report for Study E6270229

Patient: 3008

CRF: Week 12

Visit: WEEK 12

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? Y

Visit Date: 10-12-2007

Entry Time: 10-12-2007 17:22:24

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 15

Document #: R169314113

CRF Status: Created

Approver:

Verifier:

Section: Pro_Questionnair

1 of 11

Blank? Y

Section Status: Created

Visit: WEEK 12

Section Date: 10-12-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 17:22:24

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: 10-12-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 17:22:24

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: 10-12-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 17:22:24

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: 10-12-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 17:22:24

Last Modification Time:

Page number: 34

Pregnancy Test

CRF Report for Study E6270229



Patient: 3008

CRF: Week 12

Visit: WEEK 12

Site: CDB_001

Blank? Y

Visit Date: 10-12-2007

Investigator: CDB_001

CRF Page #: 15

Document #: R169314113

Section: Preg_Test	4 of 11
Date	Result

Section: Urine_Coll	5 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12	Section Date: 10-12-2007	Entry Time: 10-12-2007 17:22:24	
Entered By: Melissa Zeis	Last Modification Time:	Page number: 34	
24-Hour Urine Collection			
Scheduled Timepoint	Start Date	Start Time	Stop Date
		Stop Time	Total Volume
Comments			

Section: Hdyl_Oral_Health	6 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12	Section Date: 10-12-2007	Entry Time: 10-12-2007 17:22:24	
Entered By: Melissa Zeis	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: 10-12-2007	Entry Time: 10-12-2007 17:22:24	
Entered By: Melissa Zeis	Last Modification Time:	Page number: 35	
VITAL SIGNS			
Date	Actual Time	Blood Pressure	Oral Temperature
		Systolic Diastolic	xxx.x
		Pulse	Respiratory Rate
Unit			
Comments			

Section: Oral_Health_Exam	8 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12	Section Date: 10-12-2007	Entry Time: 10-12-2007 17:22:24	
Entered By: Melissa Zeis	Last Modification Time:	Page number: 35	
ORAL HEALTH EXAMINATION			

CRF Report for Study E6270229

Patient: 3008

CRF: Week 12

Visit: WEEK 12

Site: CDB_001

Blank? Y

Visit Date: 10-12-2007

Investigator: CDB_001

CRF Page #: 15

Document #: R169314113

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: 10-12-2007

Entry Time: 10-12-2007 17:22:24

Last Modification Time:

Page number: 36

Entered By: Melissa Zeis

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: 10-12-2007

Entry Time: 10-12-2007 17:22:24

Last Modification Time:

Page number: 36

Entered By: Melissa Zeis

WEIGHT & HEIGHT

Date

Weight

Unit

Height

Unit

xxx.x

xxx.x

Section: Lab_Eval

11 of 11

Blank? Y

Section Status: Created

Visit: WEEK 12

Section Date: 10-12-2007

Entry Time: 10-12-2007 17:22:24

Last Modification Time:

Page number: 37

Entered By: Melissa Zeis

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: 3008

CRF: Week 12(2)

Visit: WEEK 12

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? Y

Visit Date: 10-12-2007

Entry Time: 10-12-2007 17:22:31

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 16

Document #: R169314313

CRF Status: Created

Approver:

Verifier:

Section: Pk_Blood_Biomark	1 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 10-12-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:22:31	
		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: 10-12-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:22:31	
		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: 10-12-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:22:31	
		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: 10-12-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:22:31	
		Last Modification Time:	
		Page number: 38	
PRE-BRONCHODILATOR BEST BASELINE SPIROMETRY TEST RESULT			
Actual Time			

CRF Report for Study E6270229

Patient: 3008

CRF: Week 12(2)

Visit: WEEK 12

Site: CDB_001

Blank? Y

Visit Date: 10-12-2007

Investigator: CDB_001

CRF Page #: 16

Document #: R169314313

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 Status: Created
Visit: WEEK 12		Section Date: 10-12-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:22:31	
	Last Modification Time:		
	Page number: 38		
PROVENTIL ADMINISTRATION			
	Actual Time		
	of Proventil		
Date	Administration	Amount Administered	Comments

Section: Post_Bronch_Spir	6 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 10-12-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:22:31	
		Last Modification Time:	
		Page number: 38	
POST-BRONCHODILATOR BEST SPIROMETRY TEST RESULT			
	Actual Time of FEV1/FVC	Testing	
Date	Test	Position	
		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: 10-12-2007					
Entered By: Melissa Zeis				Entry Time: 10-12-2007 17:22:31					
				Last Modification Time:					
				Page number: 39					
USED STUDY TOBACCO-HEATING CIGARETTE COLLECTION									
Scheduled Collection				Number of Study					
				Tobacco-Heating					
				Cigarettes		Weight of			
				Collected		Cigarettes Collected		Any Product	
						(g)		Deviation?	
								If yes, # of other	
								Brand	
								Comments	

Section: Used_Study_Snus	8 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 10-12-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:22:31	

CRF Report for Study E6270229

Patient: 3008

CRF: Week 12(2)

Visit: WEEK 12

Site: CDB_001

Blank? Y

Visit Date: 10-12-2007

Investigator: CDB_001

CRF Page #: 16

Document #: R169314313

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
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Section: Used_Study_Bum 9 of 11

Blank? Y

Section Status: Created

Visit: WEEK 12

Section Date: 10-12-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 17:22:31

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: 10-12-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 17:22:31

Last Modification Time:

Page number: 42

USUAL STUDY TOBACCO-BURNING CIGARETTE BUTT MEASUREMENT

Date	Scheduled Collection Period	Cigarette Butt Number	Cigarette Butt Measurement (mm)
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Section: Used_Butt_Measur 11 of 11

Blank? Y

Section Status: Created

Visit: WEEK 12

Section Date: 10-12-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 17:22:31

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: 3008
CRF: Week 12(3)
Visit: WEEK 12
Entered By: Melissa Zeis
Discrepancies: None
Approval Status: Not Approved
Verification: Not Verified
Comment:

Site: CDB_001
Blank? Y
Visit Date: 10-12-2007
Entry Time: 10-12-2007 17:22:42
Modification Time:
Approval Time:
Verification Time:

Investigator: CDB_001
CRF Page #: 17
Document #: R169314513
CRF Status: Created
Approver:
Verifier:

Section: Unused_Study_Pro	1 of 2	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 10-12-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:22:42	
		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: 10-12-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:22:42	
		Last Modification Time:	
		Page number: 44	
STUDY PRODUCT DISPENSATION			
Date	Actual Time	Product Dispensed	Flavor
			Amount Dispensed

CRF Report for Study E6270229



Patient: 3008
 CRF: Week 14
 Visit: WEEK 14
 Entered By: Melissa Zeis
 Discrepancies: None
 Approval Status: Not Approved
 Verification: Not Verified
 Comment:

Site: CDB_001
 Blank? Y
 Visit Date: 10-12-2007
 Entry Time: 10-12-2007 17:22:49
 Modification Time:
 Approval Time:
 Verification Time:

Investigator: CDB_001
 CRF Page #: 18
 Document #: R169314713
 CRF Status: Created
 Approver:
 Verifier:

Section: Hdyf_Oral_Health	1 of 5	Blank? Y	Section Status: Created
Visit: WEEK 14		Section Date: 10-12-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:22:49	
		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: 10-12-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:22:49	
		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: 10-12-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:22:49	
		Last Modification Time:	
		Page number: 45	
VITAL SIGNS			
Actual Time	Blood Pressure	Oral	
	Systolic Diastolic	Temperature	
	Pulse	xxx.x	Unit
Comments			

Section: Unused_Study_Pro	4 of 5	Blank? Y	Section Status: Created
Visit: WEEK 14		Section Date: 10-12-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:22:49	
		Last Modification Time:	

CRF Report for Study E6270229

Patient: 3008

CRF: Week 14

Visit: WEEK 14

Site: CDB_001

Blank? Y

Visit Date: 10-12-2007

Investigator: CDB_001

CRF Page #: 18

Document #: R169314713

Section: Unused_Study_Pro 4 of 5

Page number: 46

Unused Study Product Returned

Product Returned	Flavor	Amount Returned	Packs	Individual Cigarettes / pouches
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Section: Study_Prod_Dispe 5 of 5

Blank? Y

Section Status: Created

Visit: WEEK 14

Section Date: 10-12-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 17:22:49

Last Modification Time:

Page number: 46

STUDY PRODUCT DISPENSATION

Actual Time	Product Dispensed	Flavor	Amount Dispensed
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CRF Report for Study E6270229

Patient: 3008

CRF: Week 16

Visit: WEEK 16

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? Y

Visit Date: 10-12-2007

Entry Time: 10-12-2007 17:22:58

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 19

Document #: R169314913

CRF Status: Created

Approver:

Verifier:

Section: Pro_Questionnair	1 of 6	Blank? Y	Section Status: Created
Visit: WEEK 16		Section Date: 10-12-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:22:58	
		Last Modification Time:	
		Page number: 47	
<p>PRO QUESTIONNAIRES</p> <p>With the possible exception of urinating, did subject complete Smoker Core Questionnaire PRIOR to any study procedures being performed?</p> <p style="text-align: right;">YES / NO</p>			

Section: Hdyf_Oral_Health	2 of 6	Blank? Y	Section Status: Created								
Visit: WEEK 16		Section Date: 10-12-2007									
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:22:58									
		Last Modification Time:									
		Page number: 47									
<p>HDYF? / ORAL HEALTH QUESTIONS INQUIRY</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;"></td> <td style="width: 20%;"></td> <td style="width: 20%;">Oral Health Questions</td> <td style="width: 40%;"></td> </tr> <tr> <td>Actual Time</td> <td>HDYF Performed?</td> <td>Performed?</td> <td>Comments</td> </tr> </table>						Oral Health Questions		Actual Time	HDYF Performed?	Performed?	Comments
		Oral Health Questions									
Actual Time	HDYF Performed?	Performed?	Comments								

Section: Vital	3 of 6	Blank? Y	Section Status: Created																		
Visit: WEEK 16		Section Date: 10-12-2007																			
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:22:58																			
		Last Modification Time:																			
		Page number: 47																			
<p>VITAL SIGNS</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%;"></td> <td style="width: 15%;">Blood Pressure</td> <td style="width: 15%;"></td> <td style="width: 15%;">Oral Temperature</td> <td style="width: 15%;"></td> <td style="width: 15%;">Unit</td> </tr> <tr> <td>Actual Time</td> <td>Systolic</td> <td>Diastolic</td> <td>Pulse</td> <td>Respiratory Rate</td> <td>xxx.x</td> </tr> <tr> <td colspan="6">Comments</td> </tr> </table>					Blood Pressure		Oral Temperature		Unit	Actual Time	Systolic	Diastolic	Pulse	Respiratory Rate	xxx.x	Comments					
	Blood Pressure		Oral Temperature		Unit																
Actual Time	Systolic	Diastolic	Pulse	Respiratory Rate	xxx.x																
Comments																					

Section: Expired_Carbon_M	4 of 6	Blank? Y	Section Status: Created
Visit: WEEK 16		Section Date: 10-12-2007	

CRF Report for Study E6270229

Patient: 3008

CRF: Week 16

Visit: WEEK 16

Site: CDB_001

Blank? Y

Visit Date: 10-12-2007

Investigator: CDB_001

CRF Page #: 19

Document #: R169314913

Section: Expired_Carbon_M 4 of 6

Entered By: Melissa Zeis

Entry Time: 10-12-2007 17:22:58

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: 10-12-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 17:22:58

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: 10-12-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 17:22:58

Last Modification Time:

Page number: 48

STUDY PRODUCT DISPENSATION

Actual Time	Product Dispensed	Flavor	Amount Dispensed
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CRF Report for Study E6270229

Patient: 3008

CRF: Week 18

Visit: WEEK 18

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? Y

Visit Date: 10-12-2007

Entry Time: 10-12-2007 17:23:05

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 20

Document #: R169315013

CRF Status: Created

Approver:

Verifier:

Section: Hdyf_Oral_Health	1 of 5	Blank? Y	Section Status: Created
Visit: WEEK 18		Section Date: 10-12-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:23:05	
		Last Modification Time:	
		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: 10-12-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:23:05	
		Last Modification Time:	
		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: 10-12-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:23:05	
		Last Modification Time:	
		Page number: 49	
VITAL SIGNS			
Actual Time	Blood Pressure	Oral	
	Systolic	Diastolic	
	Pulse	Respiratory Rate	
		Temperature	
		xxx.x	
Comments			

Section: Unused_Study_Pro	4 of 5	Blank? Y	Section Status: Created
Visit: WEEK 18		Section Date: 10-12-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:23:05	
		Last Modification Time:	

CRF Report for Study E6270229

Patient: 3008

CRF: Week 18

Visit: WEEK 18

Site: CDB_001

Blank? Y

Visit Date: 10-12-2007

Investigator: CDB_001

CRF Page #: 20

Document #: R169315013

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: 10-12-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 17:23:05

Last Modification Time:

Page number: 50

STUDY PRODUCT DISPENSATION

Actual Time	Product Dispensed	Flavor	Amount Dispensed
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Investigator: CDB 001

CRF Page #: 21

Document #: R169315113

CRF Status: Created

Modification Time:

Approver:

Verifier:

Comment:

Section:	Pro_Questionnaire	1 of 6	Blank?	Y	Section Status:	Created
Visit:	WEEK 20		Section Date:	10-12-2007		
Entered By:	Melissa Zeis		Entry Time:	10-12-2007 17:23:13		
			Last Modification Time:			
			Page number:	51		

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 20		Section Date: 10-12-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:23:13	
		Last Modification Time:	
		Page number: 51	

HDYF? / ORAL HEALTH QUESTIONS INQUIRY

Actual Time	HDYF Performed?	Oral Health Questions Performed?	Comments
-------------	-----------------	----------------------------------	----------

Section: Vital	3 of 6	Blank? Y	Section Status: Created
Visit: WEEK 20		Section Date: 10-12-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:23:13	
		Last Modification Time:	
		Page number: 51	

VITAL SIGNS

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

Section: Expired_Carbon_M	4 of 6	Blank? Y	Section Status: Created
Visit: WEEK 20		Section Date: 10-12-2007	

CRF Report for Study E6270229

Patient: 3008

CRF: Week 20

Visit: WEEK 20

Site: CDB_001

Blank? Y

Visit Date: 10-12-2007

Investigator: CDB_001

CRF Page #: 21

Document #: R169315113

Section: Expired_Carbon_M 4 of 6

Entered By: Melissa Zeis

Entry Time: 10-12-2007 17:23:13

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: 10-12-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 17:23:13

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: 10-12-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 17:23:13

Last Modification Time:

Page number: 52

STUDY PRODUCT DISPENSATION

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

CRF Report for Study E6270229

Patient: 3008

CRF: Week 22

Visit: WEEK 22

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? Y

Visit Date: 10-12-2007

Entry Time: 10-12-2007 17:23:20

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 22

Document #: R169315213

CRF Status: Created

Approver:

Verifier:

Section: Hdyf_Oral_Health	1 of 5	Blank? Y	Section Status: Created
Visit: WEEK 22		Section Date: 10-12-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:23:20	
		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: 10-12-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:23:20	
		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: 10-12-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:23:20	
		Last Modification Time:	
		Page number: 53	
VITAL SIGNS			
	Blood Pressure	Oral	
Actual Time	Systolic	Diastolic	Pulse
		Respiratory Rate	Temperature
		xxx.x	Unit
Comments			

Section: Unused_Study_Pro	4 of 5	Blank? Y	Section Status: Created
Visit: WEEK 22		Section Date: 10-12-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:23:20	
		Last Modification Time:	

CRF Report for Study E6270229

Patient: 3008

Site: CDB_001

Investigator: CDB_001

CRF: Week 22

Blank? Y

CRF Page #: 22

Visit: WEEK 22

Visit Date: 10-12-2007

Document #: R169315213

Section: Unused_Study_Pro 4 of 5

Page number: 54

Unused Study Product Returned

Product Returned	Flavor	Packs	Amount Returned Individual Cigarettes / pouches
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Section: Study_Prod_Dispe 5 of 5

Blank? Y

Section Status: Created

Visit: WEEK 22

Section Date: 10-12-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 17:23:20

Last Modification Time:

Page number: 54

STUDY PRODUCT DISPENSATION

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

CRF Report for Study E6270229

Patient: 3008

CRF: Week 24 (Eos)

Visit: WEEK 24 (EOS)

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? Y

Visit Date: 10-12-2007

Entry Time: 10-12-2007 17:23:27

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 23

Document #: R169315313

CRF Status: Created

Approver:

Verifier:

Section: Pro_Questionnair	1 of 12	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)		Section Date: 10-12-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:23:27	
		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: 10-12-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:23:27	
		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: 10-12-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:23:27	
		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: 10-12-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:23:27	
		Last Modification Time:	
		Page number: 55	
Pregnancy Test			

CRF Report for Study E6270229

Patient: 3008

CRF: Week 24 (Eos)

Visit: WEEK 24 (EOS)

Site: CDB_001

Blank? Y

Visit Date: 10-12-2007

Investigator: CDB_001

CRF Page #: 23

Document #: R169315313

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: 10-12-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 17:23:27

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: 10-12-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 17:23:27

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: Hdvf Oral Health 7 of 12

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 10-12-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 17:23:27

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: 10-12-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 17:23:27

Last Modification Time:

CRF Report for Study E6270229

Patient: 3008

CRF: Week 24 (Eos)

Visit: WEEK 24 (EOS)

Site: CDB_001

Blank? Y

Visit Date: 10-12-2007

Investigator: CDB_001

CRF Page #: 23

Document #: R169315313

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: 10-12-2007					
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:23:27					
		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: 10-12-2007					
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:23:27					
		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: 10-12-2007					
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:23:27					
		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: 10-12-2007					
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:23:27					

CRF Report for Study E6270229

Patient: 3008

Site: CDB_001

Investigator: CDB_001

CRF: Week 24 (Eos)

Blank? Y

CRF Page #: 23

Visit: WEEK 24 (EOS)

Visit Date: 10-12-2007

Document #: R169315313

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: 3008

CRF: Week 24-2 (Eos)

Visit: WEEK 24 (EOS)

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? Y

Visit Date: 10-12-2007

Entry Time: 10-12-2007 17:23:35

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 24

Document #: R169315413

CRF Status: Created

Approver:

Verifier:

Section: Pk_Blood_Biomark 1 of 11

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 10-12-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 17:23:35

Last Modification Time:

Page number: 59

Blood Sampling For Biomarkers/Chemistry/Hematology
(following an overnight fast)

Date	Actual Time	Comments
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Section: Expired_Carbon_M 2 of 11

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 10-12-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 17:23:35

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: 10-12-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 17:23:35

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: 10-12-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 17:23:35

Last Modification Time:

Page number: 60

PRE-BRONCHODILATOR BEST BASELINE SPIROMETRY TEST RESULT

Actual Time

CRF Report for Study E6270229

Patient: 3008

CRF: Week 24-2 (Eos)

Visit: WEEK 24 (EOS)

Site: CDB_001

Blank? Y

Visit Date: 10-12-2007

Investigator: CDB_001

CRF Page #: 24

Document #: R169315413

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: 10-12-2007	Section Status: Created
Visit: WEEK 24 (EOS)			Entry Time: 10-12-2007 17:23:35	
Entered By: Melissa Zeis		Last Modification Time:	Page number: 60	
PROVENTIL ADMINISTRATION				
	Actual Time of Proventil			
Date	Administration	Amount Administered		Comments

Section: Post_Bronch_Spir	6 of 11	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)		Section Date: 10-12-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:23:35	
		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: 10-12-2007	
Entered By: Melissa Zeis		Entry Time: 10-12-2007 17:23:35	
		Last Modification Time:	
		Page number: 61	
USED STUDY TOBACCO-HEATING CIGARETTE COLLECTION			
Scheduled Collection		Number of Study	
Timepoint	Start Date	Start Time	Stop Date
			Stop Time
		Cigarettes Collected	Weight of Cigarettes Collected (g)
			Any Product Deviation?
			If yes, # of other Brand
			Comments

Section: Used_Study_Snus	8 of 11	Blank? Y	Section Date: 10-12-2007	Section Status: Created
Visit: WEEK 24 (EOS)			Entry Time: 10-12-2007 17:23:35	
Entered By: Melissa Zeis				

CRF Report for Study E6270229

Patient: 3008

CRF: Week 24-2 (Eos)

Visit: WEEK 24 (EOS)

Site: CDB_001

Blank? Y

Visit Date: 10-12-2007

Investigator: CDB_001

CRF Page #: 24

Document #: R169315413

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: 10-12-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 17:23:35

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: 10-12-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 17:23:35

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: 10-12-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 17:23:35

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: 3008

CRF: Week 24-3

Visit: WEEK 24 (EOS)

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? Y

Visit Date: 10-12-2007

Entry Time: 10-12-2007 17:23:43

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 25

Document #: R169315513

CRF Status: Created

Approver:

Verifier:

Section: Unused_Study_Pro

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 10-12-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 17:23:43

Last Modification Time:

Page number: 65A

Unused Study Product Returned

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

CRF Report for Study E6270229

Patient: 3008

CRF: Precon_Med

Visit: PRECON_MEDS

Entered By: Melissa Zeis

Discrepancies: Closed

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? N

Visit Date: 10-12-2007

Entry Time: 10-12-2007 17:23:50

Modification Time: 12-12-2007 10:11:21

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 26

Document #: R169315613

CRF Status: Entry Complete

Approver:

Verifier:

Section: Pre_Conmed

Blank? N

Section Status: Entry Complete

Visit: PRECON_MEDS

Section Date: 10-12-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 17:23:50

Last Modification Time: 11-12-2007 16:55:28

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	IBUPROPHEN	UNK	UNK	PO		UNK		UNK	UNK

CRF Report for Study E6270229

Patient: 3008

CRF: AE

Visit: AE

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? N

Visit Date: 10-12-2007

Entry Time: 10-12-2007 17:24:22

Modification Time: 10-12-2007 17:24:32

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 27

Document #: R169315713

CRF Status: Entry Complete

Approver:

Verifier:

Section: Ae_Med

Blank? N

Section Status: Entry Complete

Visit: AE

Section Date: 10-12-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 17:24:22

Last Modification Time: 10-12-2007 17:24:32

Page number: 67

Adverse Events

Did the subject experience any adverse events?

NO

Event No.	Adverse Event	Onset Date	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: 3008

CRF: Ecg_Unscheduled

Visit: ECG_UNSCHEDED

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? Y

Visit Date: 10-12-2007

Entry Time: 10-12-2007 17:24:33

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 28

Document #: R169315813

CRF Status: Created

Approver:

Verifier:

Section: ECG

Blank? Y

Section Status: Created

Visit: ECG_UNSCHEDED

Section Date: 10-12-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 17:24:33

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: 3008

Site: CDB_001

Investigator: CDB_001

CRF: Lab_Unscheduled

Blank? N

CRF Page #: 29

Visit: LAB_UNSCHE

Visit Date: 10-12-2007

Document #: R169315913

Entered By: Melissa Zeis

Entry Time: 10-12-2007 17:24:43

CRF Status: Entry Complete

Discrepancies: None

Modification Time: 11-12-2007 17:34:26

Approval Status: Not Approved

Approval Time:

Approver:

Verification: Not Verified

Verification Time:

Verifier:

Comment:

Section: Lab_Eval

Blank? N

Section Status: Entry Complete

Visit: LAB_UNSCHE

Section Date: 10-12-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 17:24:43

Last Modification Time: 11-12-2007 17:34:26

Page number: 69

Unscheduled Laboratory Evaluations

Date	Requisition Number	Clinically Significant?	Test Name	High(H)/Low(L)	If Clinically Significant, Specify Lab ID	Lab Name	Comments
08-02-2007	N528237	NO					

CRF Report for Study E6270229

Patient: 3008

CRF: Vital_Unscheduled

Visit: VITAL_UNSCHEDED

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? Y

Visit Date: 10-12-2007

Entry Time: 10-12-2007 17:24:49

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 30

Document #: R169316013

CRF Status: Created

Approver:

Verifier:

Section: Vital

Blank? Y

Section Status: Created

Visit: VITAL_UNSCHEDED

Section Date: 10-12-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 17:24:49

Last Modification Time:

Page number: 70

UNSCHEDULED VITAL SIGNS

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

CRF Report for Study E6270229

Patient: 3008

Site: CDB_001

Investigator: CDB_001

CRF: Stdy_Prdt_Dis_Unschedulec

Blank? Y

CRF Page #: 31

Visit: STDY_PRDT_UNSCHE

Visit Date: 10-12-2007

Document #: R169316113

Entered By: Melissa Zeis

Entry Time: 10-12-2007 17:24:56

CRF Status: Created

Discrepancies: None

Modification Time:

Approval Status: Not Approved

Approval Time:

Approver:

Verification: Not Verified

Verification Time:

Verifier:

Comment:

Section: Study_Prod_Dispe

Blank? Y

Section Status: Created

Visit: STDY_PRDT_UNSCHE

Section Date: 10-12-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 17:24:56

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: 3008

CRF: Expired_Co2_Unscheduled

Visit: EXPIRED_CO2_UNSC

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? Y

Visit Date: 10-12-2007

Entry Time: 10-12-2007 17:25:03

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 32

Document #: R169316213

CRF Status: Created

Approver:

Verifier:

Section: Expired_Carbon_M

Blank? Y

Section Status: Created

Visit: EXPIRED_CO2_UNSC

Section Date: 10-12-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 17:25:03

Last Modification Time:

Page number: 72

UNSCHEDULED EXPIRED CARBON MONOXIDE

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

CRF Report for Study E6270229



Patient: 3008

CRF: Oral_Health_Unscheduled

Visit: ORAL_HEALTH_UNSC

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? Y

Visit Date: 10-12-2007

Entry Time: 10-12-2007 17:25:10

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 33

Document #: R169316313

CRF Status: Created

Approver:

Verifier:

Section: Oral_Health_Exam

Blank? Y

Section Status: Created

Visit: ORAL_HEALTH_UNSC

Section Date: 10-12-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 17:25:10

Last Modification Time:

Page number: 73

UNSCHEDULED ORAL HEALTH EXAMINATION

Date	Actual Time	Code	Relevant Findings?	Comment
------	-------------	------	--------------------	---------

CRF Report for Study E6270229

Patient: 3008

CRF: Spirometry_Unscheduled

Visit: SPIRO_TEST_UNSCH

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? Y

Visit Date: 10-12-2007

Entry Time: 10-12-2007 17:25:19

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 34

Document #: R169316413

CRF Status: Created

Approver:

Verifier:

Section: Pre_Bronch_Spir

Blank? Y

Section Status: Created

Visit: SPIRO_TEST_UNSCH

Section Date: 10-12-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 17:25:19

Last Modification Time:

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: 3008

CRF: Study_Completion

Visit: STUDY_COMP

Entered By: Melissa Zeis

Discrepancies: Closed

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? N

Visit Date: 10-12-2007

Entry Time: 10-12-2007 17:25:26

Modification Time: 12-12-2007 10:11:21

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 35

Document #: R169316513

CRF Status: Entry Complete

Approver:

Verifier:

Section: Study_Comp

Blank? N

Section Status: Entry Complete

Visit: STUDY_COMP

Section Date: 10-12-2007

Entered By: Melissa Zeis

Entry Time: 10-12-2007 17:25:26

Last Modification Time: 11-12-2007 11:01:54

Page number: 75

Study Completion

Did the subject complete the study?

NO

Date the subject completed OR withdrew from the study:

28-02-2007

Reason for Withdrawal

CONSENT

Specify

Investigator Comments

Principal Investigator

Full Form

Date

17 DEC 2007

Covance CLS

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

LABORATORY REPORT

ACCESSION NO. N746118

Page 1 of 3

INVESTIGATOR: (B17177)

Frank Farmer, Jr., M.D.
c/o Melissa Zeis
Covance-Daytona
1900 Mason Ave
Daytona Beach, FL 32117

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.: 3

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME: 12:20 DATE: 05-Feb-2007

DATE RECEIVED IN LABORATORY: 06-Feb-2007

DATE REPORTED BY LABORATORY: 06-Feb-2007

SEX: F BIRTHDATE: (b) (6) AGE: 41

SCREENING NUMBER: S3039

Is this Clinically
Significant/ Adverse
Event?

Yes

No

CHEMISTRY PANEL

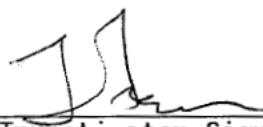
Total Bili	0.4	0.2-1.2 mg/dL
Alk Phos	79	31-106 U/L
ALT (SGPT)	10	6-34 U/L
AST (SGOT)	Hemolysis	
GGT	10	4-49 U/L
LDH	Hemolysis	
Urea Nitr	9	4-24 mg/dL
Creatinine	1.0	0.4-1.1 mg/dL
Glucose	83	70-115 mg/dL
Uric Acid	3.3	2.1-7.2 mg/dL
Calcium	9.3	8.3-10.6 mg/dL
Phosphorus	3.9	2.2-5.1 mg/dL
Total Prot	7.3	6.1-8.4 g/dL
Albumin	3.8	3.3-4.9 g/dL
Sodium	139	132-147 mEq/L
Potassium	4.8	3.4-5.4 mEq/L
Chloride	104	94-112 mEq/L

P 2-8-07

SGTOT
E SGPTto be
retested

JH

13 Feb 07


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

B17177

(INV)

Covance CLS

Marietta Henry, M.D., Director
8211 SciCor Drive - Indianapolis, IN 46214-2985
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LABORATORY REPORT

ACCESSION NO. N746118

Page 2 of 3

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INVESTIGATOR NO.: 3

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Is this Clinically
Significant/ Adverse
Event?

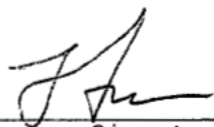
Yes

No

HEMATOLOGY& DIFFERENTIAL PANEL

HGB	13.9	11.6-16.4 g/dL
HCT	42	34-48 %
RBC	5.1	4.1-5.6x10 ⁶ /uL
MCV	83	79-98 fL
MCH	27	26-34 pg
MCHC	33	31-38 g/dL
RDW	13.6	12.0-15.0 %
RBC Morph	Normocytic	
WBC	6.54	3.80-10.70 x10 ³ /uL
Neutrophil	3.46	1.96-7.23 x10 ³ /uL
Lymphocyte	2.75	0.91-4.28 x10 ³ /uL
Monocytes	0.24	0.12-0.92 x10 ³ /uL
Eosinophil	0.06	0.00-0.57 x10 ³ /uL
Basophils	0.04	0.00-0.20 x10 ³ /uL
Neutrophil	52.8	40.5-75.0 %
Lymphocyte	42.0	15.4-48.5%
Monocytes	3.7	2.6-10.1 %
Eosinophil	0.8	0.0-6.8 %
Basophils	0.6	0.0-2.0 %
Platelets	206	140-400 x10 ³ /uL

2-8-07


Investigator Signature:

13 Feb 07
Date:

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PROTOCOL 6270-229

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RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

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DATE REPORTED BY LABORATORY: 06-Feb-2007

SEX: F BIRTHDATE: (b) (6) AGE: 41

SCREENING NUMBER: S3039

Is this Clinically
Significant/ Adverse
Event?

Yes

No

URINE MACRO & MICRO PANEL

Color	Yellow	Ref Rng:
		Colorless or Yellow
Clarity	Hazy	Ref Rng: Clear
Spec Grav	1.017	1.003-1.035
pH	5.5	5.0-8.0
Protein	Negative	Ref Rng: Negative
Glucose	Normal	Ref Rng: Normal
Ketones	Negative	Ref Rng: Negative
Bilirubin	Negative	Ref Rng: Negative
Urobilin	Normal	Ref Rng: Normal
Blood	+3 H	Ref Rng:
		Negative-Trace
Nitrite	Negative	Ref Rng: Negative
Leuk Est	Negative	Ref Rng: Negative
Microscop	Positive	

Repeat UA 2-8-08
Re-run

[]

[]

CELLULAR ELEMENTS

RBC	>150	HT	0-8 /HPF
WBC	9		0-12 /HPF

[]

[]

MICROORGANISMS

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

MISCELLANEOUS ELEMENTS

Mucous	Present	Ref Rng: Not present
--------	---------	----------------------

Investigator Signature:

Date:

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B17177

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LABORATORY REPORT

ACCESSION NO. N746118

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Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 3

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME: 12:20 DATE: 05-Feb-2007

DATE RECEIVED IN LABORATORY: 06-Feb-2007

DATE REPORTED BY LABORATORY: 06-Feb-2007

SEX: F BIRTHDATE: (b) (6) AGE: 41

SCREENING NUMBER: S3039

Is this Clinically
Significant/ Adverse
Event?

Yes

No

TOTAL IRON

Total Iron 34 30-160 ug/dL

FOLLICLE STIMULATING HORMONE

FSH 7.8

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

*2-8-07***HEPATITIS A ANTIBODY-IGM**

HepA IgMab Negative No Ref Rng


Investigator Signature:

13 Feb 07
Date:

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LABORATORY REPORT

ACCESSION NO. N746118

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Daytona Beach, FL 32117

PROTOCOL 6270-229

INVESTIGATOR NO.: 3

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: 12:20 DATE: 05-Feb-2007

DATE RECEIVED IN LABORATORY: 06-Feb-2007

DATE REPORTED BY LABORATORY: 06-Feb-2007

SEX: F BIRTHDATE: (b) (6) AGE: 41

SCREENING NUMBER: S3039

Is this Clinically
Significant/ Adverse
Event?

Yes

No

HIV 1/HIV 2 ANTIBODY SCREEN

HIV-1/2

Non-Reactive

Reference Range:
Non-Reactive

2.8-1

Investigator Signature:

13 Feb 07

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

B17177

(INV)

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Marietta Henry, M.D., Director
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LABORATORY REPORT

ACCESSION NO. N746118

Page 1 of 1

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Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 3

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME:12:20 DATE:05-Feb-2007

DATE RECEIVED IN LABORATORY: 06-Feb-2007

DATE REPORTED BY LABORATORY: 06-Feb-2007

SEX: F BIRTHDATE: (b) (6) AGE: 41

SCREENING NUMBER: S3039

Is this Clinically
Significant/ Adverse
Event?

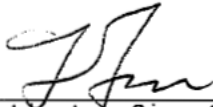
Yes

No

HEPATITIS B CORE ANTIBODY-IGM

Hep Bc IgM Negative Ref Rng:Negative

R 2-8-07


Investigator Signature:

13 Feb 07
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

B17177

(INV)

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LABORATORY REPORT

ACCESSION NO. N746118

Page 1 of 1

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SPONSOR REPORT TO:

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3402 Kinsman Boulevard
Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 3

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME: 12:20 DATE: 05-Feb-2007

DATE RECEIVED IN LABORATORY: 06-Feb-2007

DATE REPORTED BY LABORATORY: 06-Feb-2007

SEX: F BIRTHDATE: (b) (6) AGE: 41

SCREENING NUMBER: S3039

Is this Clinically
Significant/ Adverse
Event?

Yes

No

HAS PATIENT FASTED 8 HOURS?

Fasted?


Yes

IS SUBJECT A SMOKER OR NON-SM?

smoker/non

Smoker

2-8-07


Investigator Signature:

13 Feb 07
Date:

B17177

(INV)

Covance CLS

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

LABORATORY REPORT

ACCESSION NO. N746118

Page 1 of 1

INVESTIGATOR: (B17177)

Frank Farmer, Jr., M.D.
c/o Melissa Zeis
Covance-Daytona
1900 Mason Ave
Daytona Beach, FL 32117

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.: 3

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME: 12:20 DATE: 05-Feb-2007

DATE RECEIVED IN LABORATORY: 06-Feb-2007

DATE REPORTED BY LABORATORY: 07-Feb-2007

SEX: F BIRTHDATE: (b) (6) AGE: 41

SCREENING NUMBER: S3039

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

14.2

pg/mL

See Inv. Manual

15-8-07


Investigator Signature:

9 Feb 07
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

B17177

(INV)

Covance CLS
Cancellation Report
FOR DATE: 06-Feb-2007

Page 1
Feb 06, 2007 10:59:37 AM

Protocol: 6270-229 (509716)
J Reynolds Tobacco Co.
Site 140
Covance-Daytona
30 Mason Ave
Daytona Beach FL 32117

Inv #: 3
Investigator: Melissa Zeis

Accession No: N746118
Patient Number:
Patient Initials: (b)
(6)

Collection Date: 05-Feb-2007
Time: 12:20:00 PM
Visit: 1
Screen

Test
Group RC5931 CHEMISTRY PANEL
RCT1408 LDH
RCT5 AST (SGOT)

Code	Description
RCC03	Hemolysis
RCC03	Hemolysis

Handwritten signature
2-8-07

Handwritten signature
8 Feb 07

Covance CLS

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

Sponsor : R J Reynolds Tobacco Co. Investigator Name: Frank Farmer, Jr., M.D.
Protocol : 6270-229 Investigator ID : 3

Patient ID : S3039 Alert Recipient : Melissa Zeis
Patient Initials : (b) Alert Fax Number : 1-386-274-1258
Patient Sex : F
Patient DOB : (b) (6)

Visit Description: Screen Collection Date : 05-FEB-2007
Accession Number : N746118 Collection Time : 12:20

CELLULAR ELEMENTS

Test Name	Result	Reference Range	Flags
RBC	>150	0-8 /HPF	HT
RBC Clumps	Pending Result		
WBC	9	0-12 /HPF	
WBC Clumps	Pending Result		
Trans Epi	Pending Result		
Renal Epi	Pending Result		
Squam Epi	Pending Result		

Flag Key(s)

HT High - Telephone

*please**Repeat UA 2-6-07**2-8-07**John
9 Feb 07*

Covance CLS

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

ACCESSION NO. N528237

Page 1 of 2

INVESTIGATOR: (B17177)

Frank Farmer, Jr., M.D.
c/o Melissa Zeis
Covance-Daytona
1900 Mason Ave
Daytona Beach, FL 32117

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.: 3

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Retest

COLLECTION TIME: 07:02 DATE: 08-Feb-2007

DATE RECEIVED IN LABORATORY: 09-Feb-2007

DATE REPORTED BY LABORATORY: 09-Feb-2007

SEX: F BIRTHDATE: (b) (6) AGE: 41

SCREENING NUMBER: S3039

Is this Clinically
Significant/ Adverse
Event?

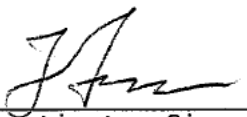
Yes

No

CHEMISTRY PANEL

Total Bili	0.3	0.2-1.2 mg/dL
Alk Phos	75	31-106 U/L
ALT (SGPT)	13	6-34 U/L
AST (SGOT)	16	9-34 U/L
GGT	10	4-49 U/L
LDH	168	53-234 U/L
Urea Nitr	13	4-24 mg/dL
Creatinine	0.9	0.4-1.1 mg/dL
Glucose	86	70-115 mg/dL
Uric Acid	3.5	2.1-7.2 mg/dL
Calcium	9.4	8.3-10.6 mg/dL
Phosphorus	4.2	2.2-5.1 mg/dL
Total Prot	7.0	6.1-8.4 g/dL
Albumin	3.9	3.3-4.9 g/dL
Sodium	143	132-147 mEq/L
Potassium	4.2	3.4-5.4 mEq/L
Chloride	106	94-112 mEq/L

2/12/07


Investigator Signature:

13 Feb 07
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

B17177

(INV)

Covance CLS

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LABORATORY REPORT

ACCESSION NO. N528237

Page 2 of 2

INVESTIGATOR: (B17177)

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 1900 Mason Ave
 Daytona Beach, FL 32117

SPONSOR REPORT TO:

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 Covance CRU, Inc.
 3402 Kinsman Boulevard
 Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 3

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Retest

COLLECTION TIME: 07:02 DATE: 08-Feb-2007

DATE RECEIVED IN LABORATORY: 09-Feb-2007

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SEX: F BIRTHDATE: (b) (6) AGE: 41

SCREENING NUMBER: S3039

Is this Clinically
 Significant/ Adverse
 Event?

Yes

No

URINE MACRO & MICRO PANEL

Color	Yellow
Clarity	Clear
Spec Grav	1.012
pH	5.0
Protein	Negative
Glucose	Normal
Ketones	Negative
Bilirubin	Negative
Urobilin	Normal
Blood	+1 H
Nitrite	Negative
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

Manner

[]

[x]

CELLULAR ELEMENTS

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

P2-12-07

[]

[x]

*Subject on
 menses. - u/A
 needs to be repeated off
 menses.*

Investigator Signature:

Date:

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LABORATORY REPORT

ACCESSION NO. N528237

Page 1 of 1

INVESTIGATOR: (B17177)

Frank Farmer, Jr., M.D.
c/o Melissa Zeis
Covance-Daytona
1900 Mason Ave
Daytona Beach, FL 32117

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.: 3

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Retest

COLLECTION TIME: 07:02 DATE: 08-Feb-2007

DATE RECEIVED IN LABORATORY: 09-Feb-2007

DATE REPORTED BY LABORATORY: 09-Feb-2007

SEX: F BIRTHDATE: (b) (6) AGE: 41

SCREENING NUMBER: S3039

Is this Clinically
Significant/ Adverse
Event?

Yes

No


TOTAL IRON

Total Iron 52 30-160 ug/dL

C-REACTIVE PROTEIN

CRP-HS 0.029 <=0.287 mg/dL

2-12-07


Investigator Signature:

13 Feb 07
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

B17177

(INV)

Covance CLS

Marietta Henry, M.D., Director
8211 SciCor Drive - Indianapolis, IN 46214-2985
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LABORATORY REPORT

**** REPRINTED: 19-FEB-2007 ****

ACCESSION NO. N528237

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Daytona Beach, FL 32117

PROTOCOL 6270-229

INVESTIGATOR NO.: 3

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

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Madison, WI United States 53704

Retest

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SEX: F BIRTHDATE: (b) (6) AGE: 41

SCREENING NUMBER: S3039

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Significant/ Adverse
Event?

Yes

No

TOTAL IRON

Total Iron 52 30-160 ug/dL

C-REACTIVE PROTEIN

CRP-HS 0.029 <=0.287 mg/dL

2-20-07

Investigator Signature:

21 Feb 07
Date:

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Event?

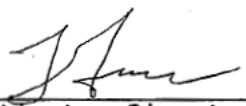
Yes

No

CHEMISTRY PANEL

Total Bili	0.3	0.2-1.2 mg/dL
Alk Phos	75	31-106 U/L
ALT (SGPT)	13	6-34 U/L
AST (SGOT)	16	9-34 U/L
GGT	10	4-49 U/L
LDH	168	53-234 U/L
Urea Nitr	13	4-24 mg/dL
Creatinine	0.9	0.4-1.1 mg/dL
Glucose	86	70-115 mg/dL
Uric Acid	3.5	2.1-7.2 mg/dL
Calcium	9.4	8.3-10.6 mg/dL
Phosphorus	4.2	2.2-5.1 mg/dL
Total Prot	7.0	6.1-8.4 g/dL
Albumin	3.9	3.3-4.9 g/dL
Sodium	143	132-147 mEq/L
Potassium	4.2	3.4-5.4 mEq/L
Chloride	106	94-112 mEq/L

2-20-07


Investigator Signature:

21 Feb 07
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 3402 Kinsman Boulevard
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PROTOCOL 6270-229

INVESTIGATOR NO.: 3

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

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DATE REPORTED BY LABORATORY: 09-Feb-2007

SEX: F BIRTHDATE: (b) (6) AGE: 41

SCREENING NUMBER: S3039

Is this Clinically
 Significant/ Adverse
 Event?

Yes

No

URINE MACRO & MICRO PANEL

Color	Yellow	Ref Rng:
		Colorless or Yellow
Clarity	Clear	Ref Rng: Clear
Spec Grav	1.012	1.003-1.035
pH	5.0	5.0-8.0
Protein	Negative	Ref Rng: Negative
Glucose	Normal	Ref Rng: Normal
Ketones	Negative	Ref Rng: Negative
Bilirubin	Negative	Ref Rng: Negative
Urobilin	Normal	Ref Rng: Normal
Blood	+1 H	Ref Rng:
		Negative-Trace
Nitrite	Negative	Ref Rng: Negative
Leuk Est	Negative	Ref Rng: Negative
Microscop	Positive	

[]

[]

CELLULAR ELEMENTS

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

[]

[]

2-20-07

Investigator Signature:

Date:

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B17177

(INV)

(b) (6)

Subject # 53039 Protocol: RJ REYNOLDS Coordinator's Name: MISSY

Time Collected: 21 FEB 2007 Time Collected: 1717 Date Tested (if different from collection date) / /

☐ H. Frank Farmer MD ☐ Other Investigator: _____

Test	Lot#	Test Exp. Date	Quality Control Performed?	Test Results	Time of Results 24 hour clock	Staff Initials
<input type="checkbox"/> Urine Pregnancy Test Brand:			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> positive <input type="checkbox"/> negative		

~~X~~ Urine Dipstick (Reagent Strip)

Brand: Mustard Lot# 6F03C Exp. Date: 12/2007 Quality Control Performed? ☒ Yes ☐ No

Glucose	Bilirubin	Ketones	Sp. Gravity	Blood	pH	Protein
NEG	NEG	NEG	1.0 <u>10</u>	2 ⁺	6	NEG
Urobilinogen	Nitrate	Leukocytes		pos 12-20		
NORMAL	NEG	NEG				

Time of Results (24 hour clock): 1735 Staff Initials: FR

Test	Lot#	Test Exp. Date	Did the Test Control Window(s) React appropriately?	Test Results	Time of Results 24 hour clock	Staff Initials
<input type="checkbox"/> Urine Cotinine/Nicotine Brand: _____			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> positive <input type="checkbox"/> negative Cut off Level: 500ng/mL		

☐ Erythrocyte Sedimentation Rate (ESR) ☐ Dispette ☐ Modified Westergren ☐ Other:

EDTA or Na Citrate well mixed before test?	Timer Used?	Start Time 24 hour clock	Stop Time 24 hour clock	Results	Note
<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	:	:	_____ mm/hr	If test is not read at exactly 60 minutes, the results are invalid and test must be repeated.

☐ Other POCT _____ Fasting? ☐ Yes ☐ No ☐ N/A

Brand: _____ Lot# _____ Exp. Date: _____ Quality Control Performed? ☐ Yes ☐ No

Test Results: ☐ positive ☐ negative ☐ Other; Result Time: Staff Initials:

Comments:

Investigator Review: _____
Signature

Date _____

Covance CLS

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

LABORATORY REPORT

ACCESSION NO. N528137

Page 1 of 1

INVESTIGATOR: (B17177)

Frank Farmer, Jr., M.D.
c/o Melissa Zeis
Covance-Daytona
1900 Mason Ave
Daytona Beach, FL 32117

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.: 3

RANDOMIZATION NUMBER: R3008

PATIENT INITIALS: (b) (6)

VISIT: 24 HR UR

24 Hr Urine Collection

COLLECTION TIME: 17:17 DATE: 21-Feb-2007

DATE RECEIVED IN LABORATORY: 24-Feb-2007

DATE REPORTED BY LABORATORY: 24-Feb-2007

SEX: F BIRTHDATE: (b) (6) AGE: 41

SCREENING NUMBER: S3039

Is this Clinically
Significant/ Adverse
Event?

Yes

No

URINE CREATININE, 24 HR

U24h Creat 1532

UA1q24Crea 43.4

600-1600 mg/24hr
mg/dL No Ref Rng

ELAPSED DATE AND TIME, 24HR

Elpsd D&T 1440

min

24 HR COLLECTION INFORMATION

Start Date 21-Feb-2007

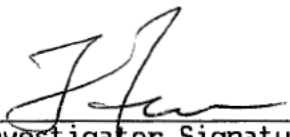
Start Time 17:17

Stop Date 22-Feb-2007

Stop Time 17:17

TOTAL 24HR URINE VOLUME

Total Vol. 3530 mL


Investigator Signature:

27 Feb 07
Date:

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(INV)

Covance CLS

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

LABORATORY REPORT

ACCESSION NO. N527187

Page 1 of 1

INVESTIGATOR: (B17177)

Frank Farmer, Jr., M.D.
c/o Melissa Zeis
Covance-Daytona
1900 Mason Ave
Daytona Beach, FL 32117

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.: 3

RANDOMIZATION NUMBER: R3008

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 06:36 DATE: 22-Feb-2007

DATE RECEIVED IN LABORATORY: 23-Feb-2007

DATE REPORTED BY LABORATORY: 19-Apr-2007

SEX: F BIRTHDATE: (b) (6) AGE: 41

SCREENING NUMBER: S3039

Is this Clinically
Significant/ Adverse
Event?

Yes

No

HOMOCYSTEINE

*1 HCY

9.75

3.36-20.44 umol/L

20 APR 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.

Julian
Investigator Signature:

20 APR 2007
Date:

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ACCESSION NO. N527187

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1900 Mason Ave

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Covance CRU, Inc.

3402 Kinsman Boulevard

Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 3

RANDOMIZATION NUMBER: R3008

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 06:36 DATE: 22-Feb-2007

DATE RECEIVED IN LABORATORY: 23-Feb-2007

DATE REPORTED BY LABORATORY: 12-Mar-2007

SEX: F BIRTHDATE: (b) (6) AGE: 41

SCREENING NUMBER: S3039

Is this Clinically
Significant/ Adverse
Event?

Yes

No

HOMOCYSTEINE

Homocys

9.75

3.36-20.11 umol/L

13.14-17

Investigator Signature:

14 MAR 07
Date:

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Marietta Henry, M.D., Director
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INVESTIGATOR: (B17177)

Frank Farmer, Jr., M.D.
c/o Melissa Zeis
Covance-Daytona
1900 Mason Ave
Daytona Beach, FL 32117

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.: 3

RANDOMIZATION NUMBER: R3008

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME:06:36 DATE:22-Feb-2007

DATE RECEIVED IN LABORATORY: 23-Feb-2007

DATE REPORTED BY LABORATORY: 02-Mar-2007

SEX: F BIRTHDATE: (b) (6) AGE: 41

SCREENING NUMBER: S3039

Is this Clinically
Significant/ Adverse
Event?

Yes

No

sICAM-1

sICAM-1

454

H

115-306 ng/mL

[]

[✓]

M
3507

F. Farmer

Investigator Signature:

06 MAR 2007
Date:

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PROTOCOL 6270-229

INVESTIGATOR NO.: 3

RANDOMIZATION NUMBER: R3008

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 06:36 DATE: 22-Feb-2007

DATE RECEIVED IN LABORATORY: 23-Feb-2007

DATE REPORTED BY LABORATORY: 24-Feb-2007

SEX: F BIRTHDATE: (b) (6) AGE: 41

SCREENING NUMBER: S3039

Is this Clinically
Significant/ Adverse
Event?

Yes

No

TOTAL IRON

Total Iron 65 30-160 ug/dL

C-REACTIVE PROTEIN

CRP-HS 0.024 <=0.287 mg/dL

CARBOXYHEMOGLOBIN

Carboxyhem 5.8 % saturation
No Ref Rng

2-26-07

[Signature]
Investigator Signature:

22 Feb 07
Date:

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PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

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DATE REPORTED BY LABORATORY: 23-Feb-2007

SEX: F BIRTHDATE: (b) (6)

AGE: 41

SCREENING NUMBER: S3039

Is this Clinically
Significant/ Adverse
Event?

Yes

No

URINE CREATININE, SPOT

Rnd Ur Crt

20

mg/dL No Ref Rng

Investigator Signature:27 Feb 07
Date:

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INVESTIGATOR NO.: 3

RANDOMIZATION NUMBER: R3008

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

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SEX: F BIRTHDATE: (b) (6) AGE: 41

SCREENING NUMBER: S3039

Is this Clinically
Significant/ Adverse
Event?


Yes

No

sICAM-1

sICAM-1

To follow

2-26-07
Investigator Signature:*27 Feb 07*
Date:

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PATIENT INITIALS: (b) (6)

VISIT: 2

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DATE REPORTED BY LABORATORY: 23-Feb-2007

SEX: F BIRTHDATE: (b) (6) AGE: 41

SCREENING NUMBER: S3039

Is this Clinically
Significant/ Adverse
Event?


Yes

No

RBC CELL WASHING (4-ABP-HB)

Wash/Store

Completed

2-24-07
Investigator Signature:*22 Feb 07*
Date:

H(High) or L(Low)=Values above or below Covance CLS reference range
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VISIT: 2

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SEX: F BIRTHDATE: (b) (6) AGE: 41

SCREENING NUMBER: S3039

Is this Clinically
Significant/ Adverse
Event?

Yes

No

HAS PATIENT FASTED 8 HOURS?

Fasted?

Yes

Handwritten signature
2-26-07

Handwritten signature: J. Farmer
Investigator Signature:

Handwritten date: 27 Feb 07
Date:

B17177

(INV)

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VISIT: 2

Week 0

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DATE REPORTED BY LABORATORY: 23-Feb-2007

SEX: F BIRTHDATE: (b) (6) AGE: 41

SCREENING NUMBER: S3039

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%

19.26.07
Investigator Signature:*27 Feb 07*
Date:

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Medical Director

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Madison, WI United States 53704

PROTOCOL 6270-229**INVESTIGATOR NO.:** 3**RANDOMIZATION NUMBER:** R3008**PATIENT INITIALS:** (b) (6)**VISIT:** 2

Week 0

COLLECTION TIME: 06:36 **DATE:** 22-Feb-2007**DATE RECEIVED IN LABORATORY:** 23-Feb-2007**DATE REPORTED BY LABORATORY:** 23-Feb-2007**SEX:** F **BIRTHDATE:** (b) (6) **AGE:** 41**SCREENING NUMBER:** S3039

Is this Clinically
Significant/ Adverse
Event?

Yes

No

LIPID PANEL

Triglycer	97		45-214 mg/dL
Cholest	148	L	155-265 mg/dL
HDL Dex-S	41		34-88 mg/dL
LDL Chol	88		74-174 mg/dL

[]

[]

22 Feb 07

J. Farmer
Investigator Signature:

22 Feb 07
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

B17177

(INV)

Covance CLS

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

LABORATORY REPORT

ACCESSION NO. N527187

Page 1 of 1

INVESTIGATOR: (B17177)

Frank Farmer, Jr., M.D.

c/o Melissa Zeis

Covance-Daytona

1900 Mason Ave

Daytona Beach, FL 32117

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.: 3

RANDOMIZATION NUMBER: R3008

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 06:36 DATE: 22-Feb-2007

DATE RECEIVED IN LABORATORY: 23-Feb-2007

DATE REPORTED BY LABORATORY: 23-Feb-2007

SEX: F BIRTHDATE: (b) (6) AGE: 41

SCREENING NUMBER: S3039

Is this Clinically
Significant/ Adverse
Event?

Yes

No

OXIDIZED LDL

OxidizeLDL

To follow

2-26-07

J. J.
Investigator Signature:

22 Feb 07
Date:

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Testing performed by: Pacific Biometrics

220 West Harrison Street; Seattle, WA 98119

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CHEMISTRY PANEL

Total Bili	0.4	0.2-1.2 mg/dL
Alk Phos	71	31-106 U/L
ALT (SGPT)	13	6-34 U/L
AST (SGOT)	17	9-34 U/L
GGT	9	4-49 U/L
LDH	159	53-234 U/L
Urea Nitr	10	4-24 mg/dL
Creatinine	0.9	0.4-1.1 mg/dL
Glucose	90	70-115 mg/dL
Uric Acid	3.2	2.1-7.2 mg/dL
Calcium	9.1	8.3-10.6 mg/dL
Phosphorus	4.1	2.2-5.1 mg/dL
Total Prot	6.7	6.1-8.4 g/dL
Albumin	3.4	3.3-4.9 g/dL
Sodium	142	132-147 mEq/L
Potassium	4.1	3.4-5.4 mEq/L
Chloride	107	94-112 mEq/L

Handwritten: 226.1

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No

HEMATOLOGY & DIFFERENTIAL PANEL

HGB	12.9	11.6-16.4 g/dL
HCT	40	34-48 %
RBC	4.8	4.1-5.6 x10 ⁶ /uL
MCV	84	79-98 fL
MCH	27	26-34 pg
MCHC	32	31-38 g/dL
RDW	14.1	12.0-15.0 %
RBC Morph	Normocytic	
WBC	5.70	3.80-10.70 x10 ³ /uL
Neutrophil	2.95	1.96-7.23 x10 ³ /uL
Lymphocyte	2.38	0.91-4.28 x10 ³ /uL
Monocytes	0.30	0.12-0.92 x10 ³ /uL
Eosinophil	0.05	0.00-0.57 x10 ³ /uL
Basophils	0.03	0.00-0.20 x10 ³ /uL
Neutrophil	51.7	40.5-75.0 %
Lymphocyte	41.7	15.4-48.5 %
Monocytes	5.3	2.6-10.1 %
Eosinophil	0.8	0.0-6.8 %
Basophils	0.5	0.0-2.0 %
Platelets	194	140-400 x10 ³ /uL

Handwritten signature
 2-26-07

Handwritten signature of J. Farmer

Investigator Signature:

Handwritten date: 27 Feb 07

Date:

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URINE MACRO & MICRO PANEL

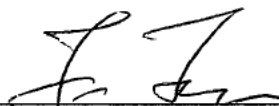
Color	Colorless	Ref Rng: Colorless or Yellow
Clarity	Clear	Ref Rng: Clear
Spec Grav	1.005	1.003-1.035
pH	5.0	5.0-8.0
Protein	Negative	Ref Rng: Negative
Glucose	Normal	Ref Rng: Normal
Ketones	Negative	Ref Rng: Negative
Bilirubin	Negative	Ref Rng: Negative
Urobilin	Normal	Ref Rng: Normal
Blood	Negative	Ref Rng: Negative-Trace
Nitrite	Negative	Ref Rng: Negative
Leuk Est	Negative	Ref Rng: Negative
Microscop	Positive	

MICROORGANISMS

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

MISCELLANEOUS ELEMENTS

Mucous	Present	Ref Rng: Not present
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Investigator Signature:

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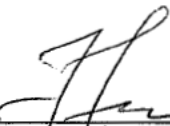
Yes

No

FIBRINOGEN

Fibrinogen 332 200-400 mg/dL

N
2-26-07



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