

# CRF Report for Study E6270229

Report run by Melissa Zeis at 23-01-2008 12:26:06

## Report on Selected Data

Filter: Site CDB\_001, Patient 3013

Legend: How different values appear in the report

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

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)

To: Covance CRU Daytona Beach  
Investigator: Frank Farmer  
Date: 06-FEB-2008

## Data Clarification Form

Patient#: 3013  
Patient Initials:  
Reviewer: Dawn Taylor

Form Name / Visit Name	Page # Date	Questions/Comments	Resolution
Informed Consent SCREENING Disc ID: 1301764513 Type: MANUAL	2 23MAR07 Closed: N	Section date for all Screening assessments is 23-03-2007, however the Informed Consent Signature date is 07-03-2007. Please verify these dates.	<input type="checkbox"/> ICD signature=23-03-2007 Screening visit=23-03-2007 <input checked="" type="checkbox"/> ICD signature=07-03-2007 Screening visit=23-03-2007 <input type="checkbox"/> ICD signature=_____ Screening visit=_____
Previous and Concomitant Medications PRECON_MEDS Disc ID: 1302200613 Type: MANUAL	26 18DEC07 Closed: N	Concomitant Medication 'Avelox' notes a dose/unit of 500 mg. Resources do not show this dosage amount as available. Please verify dose amount.	<input checked="" type="checkbox"/> 400 mg <input type="checkbox"/> 500 mg <input type="checkbox"/> Other: _____

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

Authorized Personnel Signature

Date

# CRF Report for Study E6270229

Patient: 3013  
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: 23-03-2007  
Entry Time: 05-07-2007 15:19:25  
Modification Time: 05-07-2007 15:19:43  
Approval Time:  
Verification Time:

Investigator: CDB\_001  
CRF Page #: 1  
Document #: R147573813  
CRF Status: Entry Complete  
Approver:  
Verifier:

Section: Header\_Info  
Visit: SCREENING  
Entered By: Melissa Zeis

Blank? N  
Section Date: 23-03-2007  
Entry Time: 05-07-2007 15:19:25  
Last Modification Time: 05-07-2007 15:19:43  
Page number: 1

Section Status: Entry Complete

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: 3013  
 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: 23-03-2007  
 Entry Time: 05-07-2007 15:19:44  
 Modification Time: 18-12-2007 15:34:08  
 Approval Time:  
 Verification Time:

Investigator: CDB\_001  
 CRF Page #: 2  
 Document #: R147573913  
 CRF Status: Entry Complete  
 Approver:  
 Verifier:

Section: Inc_Criteria	1 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 23-03-2007	
Entered By: Melissa Zeis		Entry Time: 05-07-2007 15:19:44	
		Last Modification Time: 05-07-2007 15:23:43	
		Page number: 2	

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

Section: Inc_Criteria	2 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 23-03-2007	
Entered By: Melissa Zeis		Entry Time: 05-07-2007 15:19:44	
		Last Modification Time: 05-07-2007 15:23:43	
		Page number: 20	

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



# CRF Report for Study E6270229

Patient: 3013

CRF: Screening

Visit: SCREENING

Site: CDB\_001

Blank? N

Visit Date: 23-03-2007

Investigator: CDB\_001

CRF Page #: 2

Document #: R147573913

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: 23-03-2007	
Entered By: Melissa Zeis			Entry Time: 05-07-2007 15:19:44	
			Last Modification Time: 05-07-2007 15:23:43	
			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 E6270229

Patient: 3013

CRF: Screening

Visit: SCREENING

Site: CDB\_001

Blank? N

Visit Date: 23-03-2007

Investigator: CDB\_001

CRF Page #: 2

Document #: R147573913

Section: Informed_Consent	4 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 23-03-2007	
Entered By: Melissa Zeis		Entry Time: 05-07-2007 15:19:44	
		Last Modification Time: 18-12-2007 15:34:08	
		Page number: 4	
Informed Consent			
Date the Subject Signed the Smoker Informed Consent Form 07-03-2007			

Section: Elig	5 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 23-03-2007	
Entered By: Melissa Zeis		Entry Time: 05-07-2007 15:19:44	
		Last Modification Time: 05-07-2007 15:23:43	
		Page number: 4	
Subject Eligibility			
Did the subject meet all of the inclusion criteria?		YES	
Did the subject have any of the exclusion criteria?		NO	
Criteria	Criteria		
Type	Number	Deviation	Date Exemption Granted

Section: Patient_Rep_Outc	6 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 23-03-2007	
Entered By: Melissa Zeis		Entry Time: 05-07-2007 15:19:44	
		Last Modification Time: 05-07-2007 15:23:43	
		Page number: 4	
Patient Reported Outcome (PRO) Questionnaires			
Did the subject complete the Smoker Screening Questionnaire prior to any study procedures being performed?			Yes / No YES

Section: Demog	7 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 23-03-2007	
Entered By: Melissa Zeis		Entry Time: 05-07-2007 15:19:44	
		Last Modification Time: 11-12-2007 11:25:52	
		Page number: 5	
Demographics		Subject Initials	
Date of Birth	Gender	Height	Height Unit
(b) (6)	F	161.3	CM
		xxx.x	
		Weight	Weight Unit
		58.0	KG
		xxx.x	
Ethnicity			

# CRF Report for Study E6270229

Patient: 3013

CRF: Screening

Visit: SCREENING

Site: CDB\_001

Blank? N

Visit Date: 23-03-2007

Investigator: CDB\_001

CRF Page #: 2

Document #: R147573913

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

Section: Vital		8 of 10		Blank? N		Section Status: Entry Complete	
Visit: SCREENING				Section Date: 23-03-2007			
Entered By: Melissa Zeis				Entry Time: 05-07-2007 15:19:44			
				Last Modification Time: 05-07-2007 15:23:43			
				Page number: 5			
VITAL SIGNS							
	Blood Pressure				Oral		
Actual Time	Systolic	Diastolic	Pulse	Respiratory Rate	Temperature	Unit	
1100	104	64	64	12	37.0	C	
					xxx.x		
Comments							

Section: Hdyf_Oral_Health		9 of 10		Blank? N		Section Status: Entry Complete	
Visit: SCREENING				Section Date: 23-03-2007			
Entered By: Melissa Zeis				Entry Time: 05-07-2007 15:19:44			
				Last Modification Time: 05-07-2007 15:23:43			
				Page number: 5			
HDYF? / ORAL HEALTH QUESTIONS INQUIRY							
			Oral Health				
			Questions				
Actual Time	HDYF Performed?		Performed?		Comments		
NR	YES		YES				

Section: Lab_Eval		10 of 10		Blank? N		Section Status: Entry Complete	
Visit: SCREENING				Section Date: 23-03-2007			
Entered By: Melissa Zeis				Entry Time: 05-07-2007 15:19:44			
				Last Modification Time: 05-07-2007 15:23:43			
				Page number: 6			
Laboratory Evaluations							
Were the scheduled laboratory samples obtained?				YES	No, specify		
Requisition Number 1		N527147					
Requisition Number 2 (if applicable)							
Were there any clinically significant labs?				NO	(Yes, specify below)		
Requisition Number	Test Name	H/L	Lab ID	Lab Name			

# CRF Report for Study E6270229

Patient: 3013

CRF: Screening2

Visit: SCREENING

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB\_001

Blank? N

Visit Date: 23-03-2007

Entry Time: 05-07-2007 15:23:44

Modification Time: 18-12-2007 15:54:17

Approval Time:

Verification Time:

Investigator: CDB\_001

CRF Page #: 3

Document #: R147575513

CRF Status: Entry Complete

Approver:

Verifier:

Section: Preg\_Test

1 of 10

Blank? N

Section Status: Entry Complete

Visit: SCREENING

Section Date: 23-03-2007

Entered By: Melissa Zeis

Entry Time: 05-07-2007 15:23:44

Last Modification Time: 05-07-2007 15:30:16

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: 23-03-2007

Entered By: Melissa Zeis

Entry Time: 05-07-2007 15:23:44

Last Modification Time: 05-07-2007 15:30:16

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: 23-03-2007

Entered By: Melissa Zeis

Entry Time: 05-07-2007 15:23:44

Last Modification Time: 05-07-2007 15:30:16

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: 23-03-2007

Entered By: Melissa Zeis

Entry Time: 05-07-2007 15:23:44

Last Modification Time: 18-12-2007 15:54:17

Page number: 7

# CRF Report for Study E6270229

Patient: 3013

CRF: Screening2

Visit: SCREENING

Site: CDB\_001

Blank? N

Visit Date: 23-03-2007

Investigator: CDB\_001

CRF Page #: 3

Document #: R147575513

Section: Med\_Hx

4 of 10

## Medical History

Does the subject have any relevant medical history?

YES

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

System	Diagnosis/Procedure	Date of Onset	Date of Resolution/Ongoing
SKIN			
EENT			
BREASTS			
RESP			
CARDIO			
LYMPH/HEMA			
GASTRO			
GENITO			
MUSCULO			
ENDOCRINE			
NEURO	MIGRAINES	00-00-1983	ONGOING
IMMUNO			
PSYCH	ANXIETY	00-02-2007	ONGOING
ALLERGIC			
OTHER			

Section: ECG

5 of 10

Blank? N

Section Status: Entry Complete

Visit: SCREENING

Section Date: 23-03-2007

Entered By: Melissa Zeis

Entry Time: 05-07-2007 15:23:44

Last Modification Time: 05-07-2007 15:30:16

Page number: 8

## 12-LEAD ELECTROCARDIOGRAM REPORT

Actual Time

Ventricular Heart Rate

1105

63

### Cardiac Cycle Measurements

PR Interval

QRS Duration

QT Interval

QTc Interval

122

88

418

423

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: 23-03-2007

Entered By: Melissa Zeis

Entry Time: 05-07-2007 15:23:44

Last Modification Time: 05-07-2007 15:30:16

# CRF Report for Study E6270229

Patient: 3013  
CRF: Screening2  
Visit: SCREENING

Site: CDB\_001  
Blank? N  
Visit Date: 23-03-2007

Investigator: CDB\_001  
CRF Page #: 3  
Document #: R147575513

Section: Usual\_Brand\_Cig 6 of 10

Page number: 9

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

Section: Ftc\_Tar\_Level 7 of 10

Blank? N

Section Status: Entry Complete

Visit: SCREENING  
Entered By: Melissa Zeis

Section Date: 23-03-2007  
Entry Time: 05-07-2007 15:23:44  
Last Modification Time: 05-07-2007 15:31:36  
Page number: 9

FTC TAR LEVEL OF USUAL BRAND  
FTC Tar Level (mg)  
8.4

Section: Expired\_Carbon\_M 8 of 10

Blank? N

Section Status: Entry Complete

Visit: SCREENING  
Entered By: Melissa Zeis

Section Date: 23-03-2007  
Entry Time: 05-07-2007 15:23:44  
Last Modification Time: 05-07-2007 15:31:36  
Page number: 10

## EXPIRED CARBON MONOXIDE

Actual Time	ECO Level (ppm)	%COHb	Comments
1052	24	4.4	

Section: Best\_Baseline\_Sp 9 of 10

Blank? N

Section Status: Entry Complete

Visit: SCREENING  
Entered By: Melissa Zeis

Section Date: 23-03-2007  
Entry Time: 05-07-2007 15:23:44  
Last Modification Time: 05-07-2007 15:31:36  
Page number: 10

## BEST BASELINE SPIROMETRY TEST RESULT

Actual Time of FEV1/FVC Test	Testing Position	FEV1 L	FEV 1 Predicted (%)	FVC L	FVC Predicted (%)	Comments
1123	STANDING	2.27	86	3.47	103	

Irvs Training 10 10

N

Entry Complete

# CRF Report for Study E6270229

Patient: 3013

CRF: Screening2

Visit: SCREENING

Site: CDB\_001

Blank? N

Visit Date: 23-03-2007

Investigator: CDB\_001

CRF Page #: 3

Document #: R147575513

Section: Irvs\_Training

10 of 10

Blank?

Section Status:

Visit: SCREENING

Section Date: 23-03-2007

Entered By: Melissa Zeis

Entry Time: 05-07-2007 15:23:44

Last Modification Time: 05-07-2007 15:31:36

Page number: 10

## IVRS TRAINING

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

YES

# CRF Report for Study E6270229

Patient: 3013

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: 03-04-2007

Entry Time: 05-07-2007 15:31:44

Modification Time: 05-07-2007 15:32:10

Approval Time:

Verification Time:

Investigator: CDB\_001

CRF Page #: 4

Document #: R147576613

CRF Status: Entry Complete

Approver:

Verifier:

Section: Usual\_Brand\_Coll

Blank? N

Section Status: Entry Complete

Visit: WEEK -2

Section Date: 03-04-2007

Entered By: Melissa Zeis

Entry Time: 05-07-2007 15:31:44

Last Modification Time: 05-07-2007 15:32:10

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: 3013

CRF: Week 0 Baseline

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: 17-04-2007

Entry Time: 05-07-2007 15:32:11

Modification Time: 18-12-2007 15:36:46

Approval Time:

Verification Time:

Investigator: CDB\_001

CRF Page #: 5

Document #: R147577213

CRF Status: Entry Complete

Approver:

Verifier:

Section: Pro_Questionnaire	1 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 17-04-2007	
Entered By: Melissa Zeis		Entry Time: 05-07-2007 15:32:11	
		Last Modification Time: 05-07-2007 15:38:57	
		Page number: 12A	
PRO QUESTIONNAIRES			
Date	1. With the possible exception of urinating, did subject	YES / NO	
17-04-2007	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: 17-04-2007	
Entered By: Melissa Zeis		Entry Time: 05-07-2007 15:32:11	
		Last Modification Time: 05-07-2007 15:38:57	
		Page number: 12A	
Drug Screen			
Date	Drug Screen Result		
17-04-2007	NEG		

Section: Alcohol_Screen	3 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 17-04-2007	
Entered By: Melissa Zeis		Entry Time: 05-07-2007 15:32:11	
		Last Modification Time: 05-07-2007 15:38:57	
		Page number: 12A	
Alcohol Screen			
Date	Breathalyzer Result		
17-04-2007	NEG		

Section: Preg_Test	4 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 17-04-2007	
Entered By: Melissa Zeis		Entry Time: 05-07-2007 15:32:11	
		Last Modification Time: 05-07-2007 15:38:57	
		Page number: 12A	

# CRF Report for Study E6270229

Patient: 3013

CRF: Week 0 Baseline

Visit: WEEK 0 (BASELINE)

Site: CDB\_001

Blank? N

Visit Date: 17-04-2007

Investigator: CDB\_001

CRF Page #: 5

Document #: R147577213

Section: Preg_Test		4 of 11	
Pregnancy Test			
Date	Result		
17-04-2007	NEGA TIVE		

Section: Urine_Coll		5 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)		Section Date: 17-04-2007					
Entered By: Melissa Zeis		Entry Time: 05-07-2007 15:32:11					
		Last Modification Time: 11-12-2007 11:37:30					
		Page number: 12A					
24-Hour Urine Collection							
Scheduled Timepoint	Start Date	Start Time	Stop Date	Stop Time	Total Volume	Comments	
SPOT URINE VOID	17-04-2007	1545	NA	NA	NA		
0 HOUR TO 24 HOURS	17-04-2007	1545	18-04-2007	1545	3430		

Section: Hdyf_Oral_Health		6 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)		Section Date: 17-04-2007					
Entered By: Melissa Zeis		Entry Time: 05-07-2007 15:32:11					
		Last Modification Time: 05-07-2007 15:38:57					
		Page number: 13.1					
HDYF? INQUIRY							
Date	Actual Time	HDYF Performed?		Comments			
18-04-2007	0618	YES					

Section: Vital		7 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)		Section Date: 17-04-2007					
Entered By: Melissa Zeis		Entry Time: 05-07-2007 15:32:11					
		Last Modification Time: 11-12-2007 11:38:40					
		Page number: 13.1					
VITAL SIGNS							
Blood Pressure							
Date	Actual Time	Systolic	Diastolic	Pulse	Respiratory Rate	Oral Temperature	Unit
17-04-2007	1555	99	57	72	16	36.7	C
						xxx.x	
Comments							

# CRF Report for Study E6270229

Patient: 3013

CRF: Week 0 Baseline

Visit: WEEK 0 (BASELINE)

Site: CDB\_001

Blank? N

Visit Date: 17-04-2007

Investigator: CDB\_001

CRF Page #: 5

Document #: R147577213

Section: Oral\_Health\_Exam 8 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 17-04-2007

Entered By: Melissa Zeis

Entry Time: 05-07-2007 15:32:11

Last Modification Time: 05-07-2007 15:38:57

Page number: 13.1

## ORAL HEALTH EXAMINATION

Date  
18-04-2007

Procedure  
ORAL HEALTH QUESTIONS PERFORMED  
EVIDENCE OF LEUKOPLAKIA  
OTHER ORAL KERATOSIS

Relevant Findings?\*

NO

NO

NO

Findings

Section: Phys\_Exam 9 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 17-04-2007

Entered By: Melissa Zeis

Entry Time: 05-07-2007 15:32:11

Last Modification Time: 18-12-2007 15:36:46

Page number: 14.1

## PHYSICAL EXAMINATION

Date  
18-04-2007

Code Number	Code
01	GENERAL
02	SKIN
03	HEENT
04	MOUTH
05	NECK
06	THORAX/LUNG
07	CARDIO
08	ABDOMEN
09	MUSCULO
10	NEURO
11	LYMPH
12	OTHER

Relevant Findings?

NO

NO

NO

NO

NO

NO

NO

NO

NO

NO

NO

NE

Findings

Section: Weight\_Height 10 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 17-04-2007

Entered By: Melissa Zeis

Entry Time: 05-07-2007 15:32:11

Last Modification Time: 05-07-2007 15:38:57

Page number: 14.1

# CRF Report for Study E6270229

Patient: 3013

CRF: Week 0 Baseline

Visit: WEEK 0 (BASELINE)

Site: CDB\_001

Blank? N

Visit Date: 17-04-2007

Investigator: CDB\_001

CRF Page #: 5

Document #: R147577213

Section: Weight\_Height 10 of 11

## WEIGHT & HEIGHT

Date	Weight	Unit	Height	Unit
17-04-2007	59.0	KG	ND	
	xxx.x		xxx.x	

Section: Lab\_Eval 11 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 17-04-2007

Entered By: Melissa Zeis

Entry Time: 05-07-2007 15:32:11

Last Modification Time: 11-12-2007 11:39:44

Page number: 15.1

## Laboratory Evaluations

Date				
18-04-2007				
Were the scheduled laboratory samples obtained?		YES	No, specify	
Requisition Number 1	N527197			
Requisition Number 2 (if applicable)				
Were there any clinically significant labs?	NO	(Yes, specify below)		
17-04-2007		YES		
	N528158			
	NO			
Requisition Number	Test Name	H/L	Lab ID	Lab Name

# CRF Report for Study E6270229

Patient: 3013  
 CRF: Week 0 2baseline  
 Visit: WEEK 0 (BASELINE)

Site: CDB\_001  
 Blank? N  
 Visit Date: 17-04-2007

Investigator: CDB\_001  
 CRF Page #: 5.1  
 Document #: R147592913  
 CRF Status: Entry Complete

Entered By: Melissa Zeis  
 Discrepancies: None  
 Approval Status: Not Approved  
 Verification: Not Verified

Entry Time: 05-07-2007 16:22:58  
 Modification Time: 11-12-2007 12:11:35  
 Approval Time:  
 Verification Time:

Approver:  
 Verifier:

Comment:

Section: Pk_Blood_Biomark	1 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 17-04-2007	
Entered By: Melissa Zeis		Entry Time: 05-07-2007 16:22:58	
		Last Modification Time: 05-07-2007 16:41:47	
		Page number: 15.1	
Blood Sampling For Biomarkers/Chemistry/Hematology (following an overnight fast)			
Date	Actual Time	Comments	
18-04-2007	0706		

Section: Expired_Carbon_M	2 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 17-04-2007	
Entered By: Melissa Zeis		Entry Time: 05-07-2007 16:22:58	
		Last Modification Time: 05-07-2007 16:41:47	
		Page number: 15.1	
EXPIRED CARBON MONOXIDE			
Date	Actual Time	ECO Level (ppm)	%COHb
18-04-2007	1321	27	4.9
Comments			

Section: Blood_Sampl_Cohb	3 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 17-04-2007	
Entered By: Melissa Zeis		Entry Time: 05-07-2007 16:22:58	
		Last Modification Time: 05-07-2007 16:41:47	
		Page number: 15.1	
Blood Sampling for %COHb			
Date	Actual Time	Comments	
18-04-2007	1323		

Section: Pre_Bronch_Spir	4 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 17-04-2007	
Entered By: Melissa Zeis		Entry Time: 05-07-2007 16:22:58	
		Last Modification Time: 05-07-2007 16:41:47	
		Page number: 16.1	

# CRF Report for Study E6270229

Patient: 3013

CRF: Week 0 2baseline

Visit: WEEK 0 (BASELINE)

Site: CDB\_001

Blank? N

Visit Date: 17-04-2007

Investigator: CDB\_001

CRF Page #: 5.1

Document #: R147592913

Section: Pre_Bronch_Spir		4 of 11					
PRE-BRONCHODILATOR BEST BASELINE SPIROMETRY TEST RESULT							
	Actual Time of FEV1/FVC	Testing Position	FEV1 L	FEV1 Predicted (%)	FVC L	FVC Predicted (%)	Comments
Date	Test						
18-04-2007	1349	STANDI NG	2.18	82	3.34	99	

Section: Proventil_Admin		5 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)				Section Date: 17-04-2007			
Entered By: Melissa Zeis				Entry Time: 05-07-2007 16:22:58			
				Last Modification Time: 05-07-2007 16:41:47			
				Page number: 16.1			
PROVENTIL ADMINISTRATION							
	Actual Time of Proventil Administration	Amount Administered		Comments			
Date							
18-04-2007	1353	2 METERED PUFFS					

Section: Post_Bronch_Spir		6 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)				Section Date: 17-04-2007			
Entered By: Melissa Zeis				Entry Time: 05-07-2007 16:22:58			
				Last Modification Time: 05-07-2007 16:41:47			
				Page number: 16.1			
POST-BRONCHODILATOR BEST SPIROMETRY TEST RESULT							
	Actual Time of FEV1/FVC	Testing Position	FEV1 L	FEV1 Predicted (%)	FVC L	FVC Predicted (%)	Comments
Date	Test						
18-04-2007	1408	STANDING	2.43	92	3.78	112	

Section: Unused_Usual_Bra		7 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)				Section Date: 17-04-2007			
Entered By: Melissa Zeis				Entry Time: 05-07-2007 16:22:58			
				Last Modification Time: 05-07-2007 16:42:02			
				Page number: 17.1			
Unused Usual Brand Cigarette Pack Collection							
						Yes / No	
Date	Does Site have 5 unopened packs of subject's usual brand cigarette to ship to CCLS?					YES	
17-04-2007							

# CRF Report for Study E6270229

Patient: 3013

CRF: Week 0 2baseline

Visit: WEEK 0 (BASELINE)

Site: CDB\_001

Blank? N

Visit Date: 17-04-2007

Investigator: CDB\_001

CRF Page #: 5.1

Document #: R147592913

Section: Usual_Brand_Butt		8 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)		Section Date: 17-04-2007		Entry Time: 05-07-2007 16:22:58			
Entered By: Melissa Zeis		Last Modification Time: 11-12-2007 12:11:35		Page number: 17.1			

Usual Brand Cigarette Butt Collection								
Scheduled Collection Period	Start Date	Start Time	Stop Date	Stop Time	Number of Usual Brand Cigarette Butts Collected	Any Product Deviation?	If yes, number of butts other than usual brand:	Comments
24 HOURS PRIOR TO CHECK-IN	16-04-2007	1500	17-04-2007	1510	17	NO		
24 HOURS IN-HOUSE	17-04-2007	1510	18-04-2007	1510	17	NO		

Section: Used_Butt_Measur		9 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)		Section Date: 17-04-2007		Entry Time: 05-07-2007 16:22:58			
Entered By: Melissa Zeis		Last Modification Time: 05-07-2007 16:44:39		Page number: 18.1			

USUAL BRAND CIGARETTE BUTT MEASUREMENT																																						
Date	Scheduled Collection Period																																					
17-04-2007	24 HOURS PRIOR TO CHECK-IN																																					
		<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Cigarette Butt Number</th> <th>Cigarette Butt Measurement (mm)</th> </tr> </thead> <tbody> <tr><td>1</td><td>45</td></tr> <tr><td>2</td><td>42</td></tr> <tr><td>3</td><td>38</td></tr> <tr><td>4</td><td>44</td></tr> <tr><td>5</td><td>44</td></tr> <tr><td>6</td><td>44</td></tr> <tr><td>7</td><td>47</td></tr> <tr><td>8</td><td>43</td></tr> <tr><td>9</td><td>48</td></tr> <tr><td>10</td><td>49</td></tr> <tr><td>11</td><td>43</td></tr> <tr><td>12</td><td>40</td></tr> <tr><td>13</td><td>46</td></tr> <tr><td>14</td><td>42</td></tr> <tr><td>15</td><td>32</td></tr> <tr><td>16</td><td>44</td></tr> <tr><td>17</td><td>47</td></tr> </tbody> </table>	Cigarette Butt Number	Cigarette Butt Measurement (mm)	1	45	2	42	3	38	4	44	5	44	6	44	7	47	8	43	9	48	10	49	11	43	12	40	13	46	14	42	15	32	16	44	17	47
Cigarette Butt Number	Cigarette Butt Measurement (mm)																																					
1	45																																					
2	42																																					
3	38																																					
4	44																																					
5	44																																					
6	44																																					
7	47																																					
8	43																																					
9	48																																					
10	49																																					
11	43																																					
12	40																																					
13	46																																					
14	42																																					
15	32																																					
16	44																																					
17	47																																					

# CRF Report for Study E6270229

Patient: 3013

CRF: Week 0 2baseline

Visit: WEEK 0 (BASELINE)

Site: CDB\_001

Blank? N

Visit Date: 17-04-2007

Investigator: CDB\_001

CRF Page #: 5.1

Document #: R147592913

Section: Used_Butt_Measur	10 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 17-04-2007	
Entered By: Melissa Zeis		Entry Time: 05-07-2007 16:22:58	
		Last Modification Time: 05-07-2007 16:49:05	
		Page number: 19.1	

## USUAL BRAND CIGARETTE BUTT MEASUREMENT

Scheduled Collection

Date  
18-04-2007

Period  
24 HOURS IN-HOUSE

Cigarette Butt Number

Cigarette Butt Measurement (mm)

1	49
2	44
3	45
4	42
5	45
6	41
7	43
8	54
9	55
10	54
11	46
12	49
13	53
14	40
15	51
16	42
17	42

Section: Randomization	11 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 17-04-2007	
Entered By: Melissa Zeis		Entry Time: 05-07-2007 16:22:58	
		Last Modification Time: 05-07-2007 16:49:43	
		Page number: 20.1	

## RANDOMIZATION

Date  
18-04-2007

Actual Time  
1513

Randomization Sequence  
GROUP B



# CRF Report for Study E6270229

Patient: 3013

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: 17-04-2007

Entry Time: 05-07-2007 16:49:48

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

Approval Time:

Verification Time:

Investigator: CDB\_001

CRF Page #: 5.2

Document #: R147606613

CRF Status: Entry Complete

Approver:

Verifier:

Section: Study\_Prod\_Dispe

Visit: WEEK 0 (BASELINE)

Entered By: Melissa Zeis

Blank? N

Section Date: 17-04-2007

Entry Time: 05-07-2007 16:49:48

Last Modification Time: 11-12-2007 12:12:43

Page number: 23.1

Section Status: Entry Complete

## STUDY PRODUCT DISPENSATION

Date	Actual Time	Product Dispensed	Flavor	Amount Dispensed
18-04-2007	1553	SNUS	SPICE	1
18-04-2007	1553	SNUS	ORIGINAL	1
18-04-2007	1553	SNUS	FROST	1

# CRF Report for Study E6270229

Patient: 3013

CRF: Intercurrent\_Ill

Visit: INTERCURRENT ILL

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB\_001

Blank? N

Visit Date: 17-04-2007

Entry Time: 05-07-2007 16:51:07

Modification Time: 05-07-2007 16:51:15

Approval Time:

Verification Time:

Investigator: CDB\_001

CRF Page #: 7

Document #: R147607713

CRF Status: Entry Complete

Approver:

Verifier:

Section: Ip\_Findings

Blank? N

Section Status: Entry Complete

Visit: INTERCURRENT ILL

Section Date: 17-04-2007

Entered By: Melissa Zeis

Entry Time: 05-07-2007 16:51:07

Last Modification Time: 05-07-2007 16:51:15

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

Event No	Illness/Finding	Date	Onset Time	Resolved / Changed Date	Time	Severity	Relationship to Procedure	Action Taken
----------	-----------------	------	---------------	----------------------------	------	----------	------------------------------	--------------

# CRF Report for Study E6270229

Patient: 3013  
 CRF: Week 1  
 Visit: WEEK 1  
 Entered By: Melissa Zeis  
 Discrepancies: None  
 Approval Status: Not Approved  
 Verification: Not Verified

Site: CDB\_001  
 Blank? N  
 Visit Date: 26-04-2007  
 Entry Time: 05-07-2007 16:51:27  
 Modification Time: 07-01-2008 18:06:55  
 Approval Time:  
 Verification Time:

Investigator: CDB\_001  
 CRF Page #: 8  
 Document #: R147608013  
 CRF Status: Entry Complete

Approver:  
 Verifier:

Comment:

Section: Hdyf_Oral_Health	1 of 5	Blank? N	Section Status: Entry Complete
Visit: WEEK 1		Section Date: 26-04-2007	
Entered By: Melissa Zeis		Entry Time: 05-07-2007 16:51:27	
		Last Modification Time: 05-07-2007 16:54:18	
		Page number: 22	
HDYF? / ORAL HEALTH QUESTIONS INQUIRY			
		Oral Health Questions	
Actual Time	HDYF Performed?	Performed?	Comments
1406	YES	YES	

Section: Vital	2 of 5	Blank? N	Section Status: Entry Complete
Visit: WEEK 1		Section Date: 26-04-2007	
Entered By: Melissa Zeis		Entry Time: 05-07-2007 16:51:27	
		Last Modification Time: 05-07-2007 16:54:18	
		Page number: 22	
VITAL SIGNS			
	Blood Pressure		Oral
Actual Time	Systolic	Diastolic	Pulse
1412	89	52	66
			Respiratory Rate
			12
			Temperature
			36.7
			xxx.x
Unit			
C			
Comments			

Section: Expired_Carbon_M	3 of 5	Blank? N	Section Status: Entry Complete
Visit: WEEK 1		Section Date: 26-04-2007	
Entered By: Melissa Zeis		Entry Time: 05-07-2007 16:51:27	
		Last Modification Time: 05-07-2007 16:54:18	
		Page number: 22	
EXPIRED CARBON MONOXIDE			
Actual Time	ECO Level (ppm)	%COHb	Comments
1413	11	2.3	

Section: Unused_Study_Pro	4 of 5	Blank? N	Section Status: Entry Complete
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# CRF Report for Study E6270229

Patient: 3013

CRF: Week 1

Visit: WEEK 1

Site: CDB\_001

Blank? N

Visit Date: 26-04-2007

Investigator: CDB\_001

CRF Page #: 8

Document #: R147608013

Section: Unused\_Study\_Pro 4 of 5

Visit: WEEK 1

Entered By: Melissa Zeis

Section Date: 26-04-2007

Entry Time: 05-07-2007 16:51:27

Last Modification Time: 05-07-2007 16:54:18

Page number: 23

## Unused Study Product Returned

Product Returned	Flavor	Amount Returned	
		Packs	Individual Cigarettes / pouches
SNUS	SPICE	0	0
SNUS	FROST	0	36
SNUS	ORIGINAL	0	40

Section: Study\_Prod\_Dispe 5 of 5

Visit: WEEK 1

Entered By: Melissa Zeis

Blank? N

Section Date: 26-04-2007

Entry Time: 05-07-2007 16:51:27

Last Modification Time: 11-12-2007 12:19:44

Page number: 23

Section Status: Entry Complete

## STUDY PRODUCT DISPENSATION

Actual Time	Product Dispensed	Flavor	Amount Dispensed
1430	SNUS	SPICE	2
1430	SNUS	ORIGINAL	1

# CRI Report for Study E6270229

Patient: 3013  
 CRF: Week 2  
 Visit: WEEK 2  
 Entered By: Melissa Zeis  
 Discrepancies: None  
 Approval Status: Not Approved  
 Verification: Not Verified

Site: CDB\_001  
 Blank? N  
 Visit Date: 03-05-2007  
 Entry Time: 05-07-2007 16:54:19  
 Modification Time: 07-01-2008 18:06:55  
 Approval Time:  
 Verification Time:

Investigator: CDB\_001  
 CRF Page #: 9  
 Document #: R147609913  
 CRF Status: Entry Complete

Approver:  
 Verifier:

## Comment:

Section: Hdyf_Oral_Health	1 of 6	Blank? N	Section Status: Entry Complete
Visit: WEEK 2		Section Date: 03-05-2007	
Entered By: Melissa Zeis		Entry Time: 05-07-2007 16:54:19	
		Last Modification Time: 05-07-2007 16:57:03	
		Page number: 24	
HDYF? / ORAL HEALTH QUESTIONS INQUIRY			
		Oral Health Questions	
Actual Time	HDYF Performed?	Performed?	Comments
1308	YES	YES	

Section: Vital	2 of 6	Blank? N	Section Status: Entry Complete
Visit: WEEK 2		Section Date: 03-05-2007	
Entered By: Melissa Zeis		Entry Time: 05-07-2007 16:54:19	
		Last Modification Time: 05-07-2007 16:57:03	
		Page number: 24	
VITAL SIGNS			
	Blood Pressure		Oral
Actual Time	Systolic	Diastolic	Pulse
1320	96	58	67
			Respiratory Rate
			16
			Temperature
			36.7
			xxx.x
			Unit
			C
Comments			

Section: Expired_Carbon_M	3 of 6	Blank? N	Section Status: Entry Complete
Visit: WEEK 2		Section Date: 03-05-2007	
Entered By: Melissa Zeis		Entry Time: 05-07-2007 16:54:19	
		Last Modification Time: 05-07-2007 16:57:03	
		Page number: 24	
EXPIRED CARBON MONOXIDE			
Actual Time	ECO Level (ppm)	%COHb	Comments
1326	3	1.1	

Section: Blood_Sampl_Cohb	4 of 6	Blank? N	Section Status: Entry Complete
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# CRF Report for Study E6270229

Patient: 3013

CRF: Week 2

Visit: WEEK 2

Site: CDB\_001

Blank? N

Visit Date: 03-05-2007

Investigator: CDB\_001

CRF Page #: 9

Document #: R147609913

Section: Blood\_Sampl\_Cohb 4 of 6

Visit: WEEK 2

Entered By: Melissa Zeis

Section Date: 03-05-2007

Entry Time: 05-07-2007 16:54:19

Last Modification Time: 05-07-2007 16:57:03

Page number: 24

Blood Sampling for %COHb

Actual Time

Comments

1335

Section: Unused\_Study\_Pro 5 of 6

Visit: WEEK 2

Entered By: Melissa Zeis

Blank? N

Section Date: 03-05-2007

Entry Time: 05-07-2007 16:54:19

Last Modification Time: 05-07-2007 16:57:03

Page number: 25

Section Status: Entry Complete

Unused Study Product Returned

Amount Returned

Product Returned	Flavor	Packs	Individual Cigarettes / pouches
SNUS	ORIGINAL	0	0
SNUS	SPICE	0	107

Section: Study\_Prod\_Dispe 6 of 6

Visit: WEEK 2

Entered By: Melissa Zeis

Blank? N

Section Date: 03-05-2007

Entry Time: 05-07-2007 16:54:19

Last Modification Time: 11-12-2007 12:19:11

Page number: 25

Section Status: Entry Complete

STUDY PRODUCT DISPENSATION

Actual Time	Product Dispensed	Flavor	Amount Dispensed
1350	SNUS	ORIGINAL	3

# CRF Report for Study E6270229

Patient: 3013

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: 11-12-2007

Entry Time: 11-12-2007 11:17:54

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB\_001

CRF Page #: 10

Document #: R169406513

CRF Status: Created

Approver:

Verifier:

Section: Pro_Questionnair	1 of 6	Blank? Y	Section Status: Created
Visit: WEEK 4		Section Date: 11-12-2007	
Entered By: Melissa Zeis		Entry Time: 11-12-2007 11:17:54	
		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: Hdvt_Oral_Health	2 of 6	Blank? Y	Section Status: Created
Visit: WEEK 4		Section Date: 11-12-2007	
Entered By: Melissa Zeis		Entry Time: 11-12-2007 11:17:54	
		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: 11-12-2007	
Entered By: Melissa Zeis		Entry Time: 11-12-2007 11:17:54	
		Last Modification Time:	
		Page number: 26	
VITAL SIGNS			
Actual Time	Blood Pressure	Oral Temperature	Unit
	Systolic Diastolic	xxx.x	
Comments			

Section: Expired_Carbon_M	4 of 6	Blank? Y	Section Status: Created
Visit: WEEK 4		Section Date: 11-12-2007	

# CRF Report for Study E6270229

Patient: 3013  
CRF: Week 4  
Visit: WEEK 4

Site: CDB\_001  
Blank? Y  
Visit Date: 11-12-2007

Investigator: CDB\_001  
CRF Page #: 10  
Document #: R169406513

Section: Expired\_Carbon\_M 4 of 6

Entered By: Melissa Zeis

Entry Time: 11-12-2007 11:17:54

Last Modification Time:

Page number: 26

## EXPIRED CARBON MONOXIDE

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

Section: Unused\_Study\_Pro 5 of 6

Blank? Y

Section Status: Created

Visit: WEEK 4

Section Date: 11-12-2007

Entered By: Melissa Zeis

Entry Time: 11-12-2007 11:17:54

Last Modification Time:

Page number: 27

## Unused Study Product Returned

Product Returned	Flavor	Packs	Amount Returned	Individual Cigarettes / pouches
------------------	--------	-------	-----------------	---------------------------------

Section: Study\_Prod\_Dispe 6 of 6

Blank? Y

Section Status: Created

Visit: WEEK 4

Section Date: 11-12-2007

Entered By: Melissa Zeis

Entry Time: 11-12-2007 11:17:54

Last Modification Time:

Page number: 27

## STUDY PRODUCT DISPENSATION

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



# CRF Report for Study E6270229

Patient: 3013  
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: 11-12-2007  
Entry Time: 11-12-2007 11:18:15  
Modification Time:  
Approval Time:  
Verification Time:

Investigator: CDB\_001  
CRF Page #: 11  
Document #: R169406713  
CRF Status: Created  
Approver:  
Verifier:

Section: Hdyf_Oral_Health	1 of 5	Blank? Y	Section Status: Created
Visit: WEEK 6		Section Date: 11-12-2007	
Entered By: Melissa Zeis		Entry Time: 11-12-2007 11:18:15	
		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: 11-12-2007	
Entered By: Melissa Zeis		Entry Time: 11-12-2007 11:18:15	
		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: 11-12-2007	
Entered By: Melissa Zeis		Entry Time: 11-12-2007 11:18:15	
		Last Modification Time:	
		Page number: 28	
VITAL SIGNS			
Actual Time	Blood Pressure	Oral	
	Systolic	Diastolic	
	Pulse	Respiratory Rate	
		Temperature	
		xxx.x	
Unit			
Comments			

Section: Unused_Study_Pro	4 of 5	Blank? Y	Section Status: Created
Visit: WEEK 6		Section Date: 11-12-2007	
Entered By: Melissa Zeis		Entry Time: 11-12-2007 11:18:15	
		Last Modification Time:	

# CRF Report for Study E6270229

Patient: 3013

CRF: Week 6

Visit: WEEK 6

Site: CDB\_001

Blank? Y

Visit Date: 11-12-2007

Investigator: CDB\_001

CRF Page #: 11

Document #: R169406713

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: 11-12-2007

Entered By: Melissa Zeis

Entry Time: 11-12-2007 11:18:15

Last Modification Time:

Page number: 29

## STUDY PRODUCT DISPENSATION

Actual Time

Product Dispensed

Flavor

Amount Dispensed

# CRF Report for Study E6270229

Patient: 3013  
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: 11-12-2007  
Entry Time: 11-12-2007 11:18:22  
Modification Time:  
Approval Time:  
Verification Time:

Investigator: CDB\_001  
CRF Page #: 13  
Document #: R169406813  
CRF Status: Created  
Approver:  
Verifier:

Section: Pro_Questionnair	1 of 6	Blank? Y	Section Status: Created
Visit: WEEK 8		Section Date: 11-12-2007	
Entered By: Melissa Zeis		Entry Time: 11-12-2007 11:18:22	
		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: Hdvf_Oral_Health	2 of 6	Blank? Y	Section Status: Created
Visit: WEEK 8		Section Date: 11-12-2007	
Entered By: Melissa Zeis		Entry Time: 11-12-2007 11:18:22	
		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: 11-12-2007	
Entered By: Melissa Zeis		Entry Time: 11-12-2007 11:18:22	
		Last Modification Time:	
		Page number: 30	
VITAL SIGNS			
Actual Time	Blood Pressure		Oral
	Systolic	Diastolic	Pulse
			Respiratory Rate
			Temperature
			xxx.x
Unit			
Comments			

Section: Expired_Carbon_M	4 of 6	Blank? Y	Section Status: Created
Visit: WEEK 8		Section Date: 11-12-2007	

# CRF Report for Study E6270229

Patient: 3013  
CRF: Week 8  
Visit: WEEK 8

Site: CDB\_001  
Blank? Y  
Visit Date: 11-12-2007

Investigator: CDB\_001  
CRF Page #: 13  
Document #: R169406813

Section: Expired\_Carbon\_M 4 of 6

Entered By: Melissa Zeis

Entry Time: 11-12-2007 11:18:22

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: 11-12-2007

Entered By: Melissa Zeis

Entry Time: 11-12-2007 11:18:22

Last Modification Time:

Page number: 31

## Unused Study Product Returned

Product Returned	Flavor	Amount Returned	
		Packs	Individual Cigarettes / pouches

Section: Study\_Prod\_Dispe 6 of 6

Blank? Y

Section Status: Created

Visit: WEEK 8

Section Date: 11-12-2007

Entered By: Melissa Zeis

Entry Time: 11-12-2007 11:18:22

Last Modification Time:

Page number: 31

## STUDY PRODUCT DISPENSATION

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

# CRF Report for Study E6270229



Patient: 3013  
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: 11-12-2007  
Entry Time: 11-12-2007 11:18:32  
Modification Time:  
Approval Time:  
Verification Time:

Investigator: CDB\_001  
CRF Page #: 14  
Document #: R169406913  
CRF Status: Created  
Approver:  
Verifier:

Section: Hdyf_Oral_Health	1 of 5	Blank? Y	Section Status: Created
Visit: WEEK 10		Section Date: 11-12-2007	
Entered By: Melissa Zeis		Entry Time: 11-12-2007 11:18:32	
		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: 11-12-2007	
Entered By: Melissa Zeis		Entry Time: 11-12-2007 11:18:32	
		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: 11-12-2007	
Entered By: Melissa Zeis		Entry Time: 11-12-2007 11:18:32	
		Last Modification Time:	
		Page number: 32	
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 10		Section Date: 11-12-2007	
Entered By: Melissa Zeis		Entry Time: 11-12-2007 11:18:32	
		Last Modification Time:	

# CRF Report for Study E6270229

Patient: 3013

CRF: Week 10

Visit: WEEK 10

Site: CDB\_001

Blank? Y

Visit Date: 11-12-2007

Investigator: CDB\_001

CRF Page #: 14

Document #: R169406913

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: 11-12-2007

Entered By: Melissa Zeis

Entry Time: 11-12-2007 11:18:32

Last Modification Time:

Page number: 33

## STUDY PRODUCT DISPENSATION

Actual Time

Product Dispensed

Flavor

Amount Dispensed

# CRF Report for Study E6270229

Patient: 3013

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: 11-12-2007

Entry Time: 11-12-2007 11:18:39

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB\_001

CRF Page #: 15

Document #: R169407013

CRF Status: Created

Approver:

Verifier:

Section: Pro_Questionnaire	1 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 11-12-2007	
Entered By: Melissa Zeis		Entry Time: 11-12-2007 11:18:39	
		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: 11-12-2007	
Entered By: Melissa Zeis		Entry Time: 11-12-2007 11:18:39	
		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: 11-12-2007	
Entered By: Melissa Zeis		Entry Time: 11-12-2007 11:18:39	
		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: 11-12-2007	
Entered By: Melissa Zeis		Entry Time: 11-12-2007 11:18:39	
		Last Modification Time:	
		Page number: 34	
Pregnancy Test			

# CRF Report for Study E6270229

Patient: 3013  
CRF: Week 12  
Visit: WEEK 12

Site: CDB\_001  
Blank? Y  
Visit Date: 11-12-2007

Investigator: CDB\_001  
CRF Page #: 15  
Document #: R169407013

Section: Preg_Test	4 of 11
Date	Result

Section: Urine_Coll	5 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 11-12-2007	
Entered By: Melissa Zeis		Entry Time: 11-12-2007 11:18:39	
		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: 11-12-2007	
Entered By: Melissa Zeis		Entry Time: 11-12-2007 11:18:39	
		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: 11-12-2007	
Entered By: Melissa Zeis		Entry Time: 11-12-2007 11:18:39	
		Last Modification Time:	
		Page number: 35	
VITAL SIGNS			
		Blood Pressure	Oral
Date	Actual Time	Systolic	Diastolic
		Pulse	Respiratory Rate
			Temperature
			xxx.x
Unit			
Comments			

Section: Oral_Health_Exam	8 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 11-12-2007	
Entered By: Melissa Zeis		Entry Time: 11-12-2007 11:18:39	
		Last Modification Time:	
		Page number: 35	
ORAL HEALTH EXAMINATION			



# CRF Report for Study E6270229

Patient: 3013  
CRF: Week 12  
Visit: WEEK 12

Site: CDB\_001  
Blank? Y  
Visit Date: 11-12-2007

Investigator: CDB\_001  
CRF Page #: 15  
Document #: R169407013

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: 11-12-2007	
Entered By: Melissa Zeis		Entry Time: 11-12-2007 11:18:39	
		Last Modification Time:	
		Page number: 36	
PHYSICAL EXAMINATION			
Date	Code Number	Code	Relevant Findings?
			Findings

Section: Weight_Height	10 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 11-12-2007	
Entered By: Melissa Zeis		Entry Time: 11-12-2007 11:18:39	
		Last Modification Time:	
		Page number: 36	
WEIGHT & HEIGHT			
Date	Weight	Unit	Height
	xxx.x		xxx.x

Section: Lab_Eval	11 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 11-12-2007	
Entered By: Melissa Zeis		Entry Time: 11-12-2007 11:18:39	
		Last Modification Time:	
		Page number: 37	
Laboratory Evaluations			
Date			
Were the scheduled laboratory samples obtained?	No, specify		
Requisition Number 1			
Requisition Number 2 (if applicable)			
Were there any clinically significant labs?	(Yes, specify below)		
Requisition Number	Test Name	H/L	Lab ID
			Lab Name

# CRF Report for Study E6270229

Patient: 3013

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: 11-12-2007

Entry Time: 11-12-2007 11:18:47

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB\_001

CRF Page #: 16

Document #: R169407113

CRF Status: Created

Approver:

Verifier:

Section: Pk_Blood_Biomark	1 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12	Section Date: 11-12-2007		
Entered By: Melissa Zeis	Entry Time: 11-12-2007 11:18:47		
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: 11-12-2007		
Entered By: Melissa Zeis	Entry Time: 11-12-2007 11:18:47		
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: 11-12-2007		
Entered By: Melissa Zeis	Entry Time: 11-12-2007 11:18:47		
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: 11-12-2007		
Entered By: Melissa Zeis	Entry Time: 11-12-2007 11:18:47		
Last Modification Time:			
Page number: 38			
PRE-BRONCHODILATOR BEST BASELINE SPIROMETRY TEST RESULT			
Actual Time			

# CRF Report for Study E6270229

Patient: 3013  
CRF: Week 12(2)  
Visit: WEEK 12

Site: CDB\_001  
Blank? Y  
Visit Date: 11-12-2007

Investigator: CDB\_001  
CRF Page #: 16  
Document #: R169407113

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: 11-12-2007		Entry Time: 11-12-2007 11:18:47			
Entered By: Melissa Zeis		Last Modification Time:		Page number: 38			

PROVENTIL ADMINISTRATION							
Actual Time of Proventil Administration		Amount Administered		Comments			
Date							

Section: Post_Bronch_Spir		6 of 11		Blank? Y		Section Status: Created	
Visit: WEEK 12		Section Date: 11-12-2007		Entry Time: 11-12-2007 11:18:47			
Entered By: Melissa Zeis		Last Modification Time:		Page number: 38			

POST-BRONCHODILATOR BEST SPIROMETRY TEST RESULT							
Date	Actual Time of FEV1/FVC Test	Testing 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: 11-12-2007		Entry Time: 11-12-2007 11:18:47			
Entered By: Melissa Zeis		Last Modification Time:		Page number: 39			

USED STUDY TOBACCO-HEATING CIGARETTE COLLECTION									
					Number of Study Tobacco-Heating	Weight of			
Scheduled Collection			Stop	Stop	Cigarettes	Cigarettes Collected	Any Product	If yes, # of other	
Timepoint	Start Date	Start Time	Date	Time	Collected	(g)	Deviation?	Brand	Comments

Section: Used_Study_Snus	8 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 11-12-2007	
Entered By: Melissa Zeis		Entry Time: 11-12-2007 11:18:47	

# CRF Report for Study E6270229

Patient: 3013  
CRF: Week 12(2)  
Visit: WEEK 12

Site: CDB\_001  
Blank? Y  
Visit Date: 11-12-2007

Investigator: CDB\_001  
CRF Page #: 16  
Document #: R169407113

Section: Used\_Study\_Snus 8 of 11

Last Modification Time:  
Page number: 40

## USED STUDY SNUS COLLECTION

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

Section: Used\_Study\_Burn 9 of 11

Blank? Y

Section Status: Created

Visit: WEEK 12  
Entered By: Melissa Zeis

Section Date: 11-12-2007  
Entry Time: 11-12-2007 11:18:47

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  
Entered By: Melissa Zeis

Section Date: 11-12-2007  
Entry Time: 11-12-2007 11:18:47

Last Modification Time:  
Page number: 42

## USUAL STUDY TOBACCO-BURNING CIGARETTE BUTT MEASUREMENT

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

Section: Used\_Butt\_Measur 11 of 11

Blank? Y

Section Status: Created

Visit: WEEK 12  
Entered By: Melissa Zeis

Section Date: 11-12-2007  
Entry Time: 11-12-2007 11:18:47

Last Modification Time:  
Page number: 43

## USED STUDY TOBACCO-BURNING CIGARETTE BUTT MEASUREMENT

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

# CRF Report for Study E6270229

Patient: 3013

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: 11-12-2007

Entry Time: 11-12-2007 11:18:56

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB\_001

CRF Page #: 17

Document #: R169407213

CRF Status: Created

Approver:

Verifier:

Section: Unused_Study_Pro	1 of 2	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 11-12-2007	
Entered By: Melissa Zeis		Entry Time: 11-12-2007 11:18:56	
		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: 11-12-2007	
Entered By: Melissa Zeis		Entry Time: 11-12-2007 11:18:56	
		Last Modification Time:	
		Page number: 44	
STUDY PRODUCT DISPENSATION			
Date	Actual Time	Product Dispensed	Flavor
			Amount Dispensed

# CRF Report for Study E6270229

Patient: 3013

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: 11-12-2007

Entry Time: 11-12-2007 11:19:04

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB\_001

CRF Page #: 18

Document #: R169407413

CRF Status: Created

Approver:

Verifier:

Section: Hdyf_Oral_Health	1 of 5	Blank? Y	Section Status: Created
Visit: WEEK 14		Section Date: 11-12-2007	
Entered By: Melissa Zeis		Entry Time: 11-12-2007 11:19:04	
		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: 11-12-2007	
Entered By: Melissa Zeis		Entry Time: 11-12-2007 11:19:04	
		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: 11-12-2007	
Entered By: Melissa Zeis		Entry Time: 11-12-2007 11:19:04	
		Last Modification Time:	
		Page number: 45	
VITAL SIGNS			
	Blood Pressure		Oral
Actual Time	Systolic	Diastolic	Temperature
		Pulse	xxx.x
		Respiratory Rate	Unit
Comments			

Section: Unused_Study_Pro	4 of 5	Blank? Y	Section Status: Created
Visit: WEEK 14		Section Date: 11-12-2007	
Entered By: Melissa Zeis		Entry Time: 11-12-2007 11:19:04	
		Last Modification Time:	

# CRF Report for Study E6270229

Patient: 3013

CRF: Week 14

Visit: WEEK 14

Site: CDB\_001

Blank? Y

Visit Date: 11-12-2007

Investigator: CDB\_001

CRF Page #: 18

Document #: R169407413

Section: Unused\_Study\_Pro 4 of 5

Page number: 46

## Unused Study Product Returned

Product Returned

Flavor

Amount Returned

Packs

Individual Cigarettes / pouches

Section: Study\_Prod\_Dispe

5 of 5

Blank? Y

Section Status: Created

Visit: WEEK 14

Section Date: 11-12-2007

Entered By: Melissa Zeis

Entry Time: 11-12-2007 11:19:04

Last Modification Time:

Page number: 46

## STUDY PRODUCT DISPENSATION

Actual Time

Product Dispensed

Flavor

Amount Dispensed

# CRF Report for Study E6270229

Patient: 3013

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: 11-12-2007

Entry Time: 11-12-2007 11:19:12

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB\_001

CRF Page #: 19

Document #: R169407513

CRF Status: Created

Approver:

Verifier:

Section: Pro_Questionnair	1 of 6	Blank? Y	Section Status: Created
Visit: WEEK 16		Section Date: 11-12-2007	
Entered By: Melissa Zeis		Entry Time: 11-12-2007 11:19:12	
		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: 11-12-2007									
Entered By: Melissa Zeis		Entry Time: 11-12-2007 11:19:12									
		Last Modification Time:									
		Page number: 47									
<p>HDYF? / ORAL HEALTH QUESTIONS INQUIRY</p> <table style="width: 100%; border: none;"> <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: 11-12-2007																						
Entered By: Melissa Zeis		Entry Time: 11-12-2007 11:19:12																						
		Last Modification Time:																						
		Page number: 47																						
<p>VITAL SIGNS</p> <table style="width: 100%; border: none;"> <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%;"></td> <td style="width: 10%;"></td> </tr> <tr> <td>Actual Time</td> <td>Systolic</td> <td>Diastolic</td> <td>Pulse</td> <td>Respiratory Rate</td> <td>xxx.x</td> <td>Unit</td> </tr> <tr> <td colspan="7">Comments</td> </tr> </table>					Blood Pressure		Oral Temperature				Actual Time	Systolic	Diastolic	Pulse	Respiratory Rate	xxx.x	Unit	Comments						
	Blood Pressure		Oral Temperature																					
Actual Time	Systolic	Diastolic	Pulse	Respiratory Rate	xxx.x	Unit																		
Comments																								

Section: Expired_Carbon_M	4 of 6	Blank? Y	Section Status: Created
Visit: WEEK 16		Section Date: 11-12-2007	



# CRF Report for Study E6270229

Patient: 3013  
CRF: Week 16  
Visit: WEEK 16

Site: CDB\_001  
Blank? Y  
Visit Date: 11-12-2007

Investigator: CDB\_001  
CRF Page #: 19  
Document #: R169407513

Section: Expired\_Carbon\_M 4 of 6

Entered By: Melissa Zeis

Entry Time: 11-12-2007 11:19:12

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: 11-12-2007

Entered By: Melissa Zeis

Entry Time: 11-12-2007 11:19:12

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: 11-12-2007

Entered By: Melissa Zeis

Entry Time: 11-12-2007 11:19:12

Last Modification Time:

Page number: 48

## STUDY PRODUCT DISPENSATION

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

# CRF Report for Study E6270229

Patient: 3013

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: 11-12-2007

Entry Time: 11-12-2007 11:19:22

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB\_001

CRF Page #: 20

Document #: R169407613

CRF Status: Created

Approver:

Verifier:

Section: Hdyf_Oral_Health	1 of 5	Blank? Y	Section Status: Created
Visit: WEEK 18		Section Date: 11-12-2007	
Entered By: Melissa Zeis		Entry Time: 11-12-2007 11:19:22	
		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: 11-12-2007	
Entered By: Melissa Zeis		Entry Time: 11-12-2007 11:19:22	
		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: 11-12-2007	
Entered By: Melissa Zeis		Entry Time: 11-12-2007 11:19:22	
		Last Modification Time:	
		Page number: 49	
VITAL SIGNS			
Actual Time	Blood Pressure	Oral Temperature	Unit
	Systolic Diastolic	xxx.x	
Comments	Pulse	Respiratory Rate	

Section: Unused_Study_Pro	4 of 5	Blank? Y	Section Status: Created
Visit: WEEK 18		Section Date: 11-12-2007	
Entered By: Melissa Zeis		Entry Time: 11-12-2007 11:19:22	
		Last Modification Time:	

# CRF Report for Study E6270229

Patient: 3013

CRF: Week 18

Visit: WEEK 18

Site: CDB\_001

Blank? Y

Visit Date: 11-12-2007

Investigator: CDB\_001

CRF Page #: 20

Document #: R169407613

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: 11-12-2007

Entered By: Melissa Zeis

Entry Time: 11-12-2007 11:19:22

Last Modification Time:

Page number: 50

## STUDY PRODUCT DISPENSATION

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

# CRF Report for Study E6270229

Patient: 3013

CRF: Week 20

Visit: WEEK 20

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB\_001

Blank? Y

Visit Date: 11-12-2007

Entry Time: 11-12-2007 11:19:29

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB\_001

CRF Page #: 21

Document #: R169407713

CRF Status: Created

Approver:

Verifier:

Section: Pro_Questionnaire	1 of 6	Blank? Y	Section Status: Created
Visit: WEEK 20		Section Date: 11-12-2007	
Entered By: Melissa Zeis		Entry Time: 11-12-2007 11:19:29	
		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: 11-12-2007	
Entered By: Melissa Zeis		Entry Time: 11-12-2007 11:19:29	
		Last Modification Time:	
		Page number: 51	
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 20		Section Date: 11-12-2007	
Entered By: Melissa Zeis		Entry Time: 11-12-2007 11:19:29	
		Last Modification Time:	
		Page number: 51	
VITAL SIGNS			
Actual Time	Blood Pressure	Oral Temperature	Unit
	Systolic Diastolic	xxx.x	
	Pulse	Respiratory Rate	
Comments			

Section: Expired_Carbon_M	4 of 6	Blank? Y	Section Status: Created
Visit: WEEK 20		Section Date: 11-12-2007	

# CRF Report for Study E6270229

Patient: 3013  
CRF: Week 20  
Visit: WEEK 20

Site: CDB\_001  
Blank? Y  
Visit Date: 11-12-2007

Investigator: CDB\_001  
CRF Page #: 21  
Document #: R169407713

Section: Expired\_Carbon\_M 4 of 6

Entered By: Melissa Zeis

Entry Time: 11-12-2007 11:19:29

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: 11-12-2007

Entered By: Melissa Zeis

Entry Time: 11-12-2007 11:19:29

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: 11-12-2007

Entered By: Melissa Zeis

Entry Time: 11-12-2007 11:19:29

Last Modification Time:

Page number: 52

## STUDY PRODUCT DISPENSATION

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

# CRF Report for Study E6270229

Patient: 3013

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: 11-12-2007

Entry Time: 11-12-2007 11:19:37

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB\_001

CRF Page #: 22

Document #: R169408013

CRF Status: Created

Approver:

Verifier:

Section: Hdyf_Oral_Health	1 of 5	Blank? Y	Section Status: Created
Visit: WEEK 22		Section Date: 11-12-2007	
Entered By: Melissa Zeis		Entry Time: 11-12-2007 11:19:37	
		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: 11-12-2007	
Entered By: Melissa Zeis		Entry Time: 11-12-2007 11:19:37	
		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: 11-12-2007	
Entered By: Melissa Zeis		Entry Time: 11-12-2007 11:19:37	
		Last Modification Time:	
		Page number: 53	
VITAL SIGNS			
Actual Time	Blood Pressure	Oral Temperature	Unit
	Systolic Diastolic	xxx.x	
Comments			

Section: Unused_Study_Pro	4 of 5	Blank? Y	Section Status: Created
Visit: WEEK 22		Section Date: 11-12-2007	
Entered By: Melissa Zeis		Entry Time: 11-12-2007 11:19:37	
		Last Modification Time:	

# CRF Report for Study E6270229

Patient: 3013

CRF: Week 22

Visit: WEEK 22

Site: CDB\_001

Blank? Y

Visit Date: 11-12-2007

Investigator: CDB\_001

CRF Page #: 22

Document #: R169408013

Section: Unused\_Study\_Pro

4 of 5

Page number: 54

## Unused Study Product Returned

Product Returned

Flavor

Amount Returned

Packs

Individual Cigarettes / pouches

Section: Study\_Prod\_Dispe

5 of 5

Blank? Y

Section Status: Created

Visit: WEEK 22

Section Date: 11-12-2007

Entered By: Melissa Zeis

Entry Time: 11-12-2007 11:19:37

Last Modification Time:

Page number: 54

## STUDY PRODUCT DISPENSATION

Actual Time

Product Dispensed

Flavor

Amount Dispensed

# CRF Report for Study E6270229

Patient: 3013

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? N

Visit Date: 29-05-2007

Entry Time: 05-07-2007 16:57:32

Modification Time: 18-12-2007 15:37:37

Approval Time:

Verification Time:

Investigator: CDB\_001

CRF Page #: 23

Document #: R147611913

CRF Status: Entry Complete

Approver:

Verifier:

Section: Pro_Questionnair	1 of 12	Blank? N	Section Status: Entry Complete
Visit: WEEK 24 (EOS)		Section Date: 29-05-2007	
Entered By: Melissa Zeis		Entry Time: 05-07-2007 16:57:32	
		Last Modification Time: 05-07-2007 17:05:32	
		Page number: 55	
PRO QUESTIONNAIRES			
Date	1. With the possible exception of urinating, did subject	YES / NO	
29-05-2007	complete Smoker Routine Questionnaire PRIOR to any		
	study procedures being performed?	YES	

Section: Urine_Drug	2 of 12	Blank? N	Section Status: Entry Complete
Visit: WEEK 24 (EOS)		Section Date: 29-05-2007	
Entered By: Melissa Zeis		Entry Time: 05-07-2007 16:57:32	
		Last Modification Time: 11-12-2007 12:40:17	
		Page number: 55	
Drug Screen			
Date	Drug Screen Result		
29-05-2007	POS		

Section: Alcohol_Screen	3 of 12	Blank? N	Section Status: Entry Complete
Visit: WEEK 24 (EOS)		Section Date: 29-05-2007	
Entered By: Melissa Zeis		Entry Time: 05-07-2007 16:57:32	
		Last Modification Time: 05-07-2007 17:05:32	
		Page number: 55	
Alcohol Screen			
Date	Breathalyzer Result		
29-05-2007	ND		

Section: Preg_Test	4 of 12	Blank? N	Section Status: Entry Complete
Visit: WEEK 24 (EOS)		Section Date: 29-05-2007	
Entered By: Melissa Zeis		Entry Time: 05-07-2007 16:57:32	
		Last Modification Time: 05-07-2007 17:05:32	
		Page number: 55	



# CRF Report for Study E6270229

Patient: 3013

CRF: Week 24 (Eos)

Visit: WEEK 24 (EOS)

Site: CDB\_001

Blank? N

Visit Date: 29-05-2007

Investigator: CDB\_001

CRF Page #: 23

Document #: R147611913

Section: Preg\_Test 4 of 12

Pregnancy Test

Date

29-05-2007

Result

NEGA

TIVE

Section: Urine\_Coll 5 of 12

Blank? N

Section Status: Entry Complete

Visit: WEEK 24 (EOS)

Section Date: 29-05-2007

Entered By: Melissa Zeis

Entry Time: 05-07-2007 16:57:32

Last Modification Time: 11-12-2007 13:01:17

Page number: 55

24-Hour Urine Collection

Scheduled Timepoint	Start Date	Start Time	Stop Date	Stop Time	Total Volume	Comments
SPOT URINE VOID	NA	NA	NA	NA	NA	
0 HOUR TO 24 HOURS	NA	NA	NA	NA	NA	

Section: ECG 6 of 12

Blank? N

Section Status: Entry Complete

Visit: WEEK 24 (EOS)

Section Date: 29-05-2007

Entered By: Melissa Zeis

Entry Time: 05-07-2007 16:57:32

Last Modification Time: 05-07-2007 17:05:32

Page number: 56

12-LEAD ELECTROCARDIOGRAM REPORT

Actual Time

1149

Ventricular Heart Rate

64

Cardiac Cycle Measurements

PR Interval

122

QRS Duration

90

QT Interval

402

QTc Interval

407

ECG INTERPRETATION:

ANCS

Comments (related to abnormal, CS findings only):

Section: Hdyf\_Oral\_Health 7 of 12

Blank? N

Section Status: Entry Complete

Visit: WEEK 24 (EOS)

Section Date: 29-05-2007

Entered By: Melissa Zeis

Entry Time: 05-07-2007 16:57:32

Last Modification Time: 11-12-2007 13:06:54

Page number: 57

HDYF? / ORAL HEALTH QUESTIONS INQUIRY

Oral Health

# CRF Report for Study E6270229

Patient: 3013

CRF: Week 24 (Eos)

Visit: WEEK 24 (EOS)

Site: CDB\_001

Blank? N

Visit Date: 29-05-2007

Investigator: CDB\_001

CRF Page #: 23

Document #: R147611913

Section: Hdyf_Oral_Health		7 of 12		
Date	Actual Time	HDYF Performed?	Questions Performed?	Comments
29-05-2007	UNK	YES	YES	

Section: Vital	8 of 12	Blank? N	Section Status: Entry Complete
Visit: WEEK 24 (EOS)		Section Date: 29-05-2007	
Entered By: Melissa Zeis		Entry Time: 05-07-2007 16:57:32	
		Last Modification Time: 05-07-2007 17:05:32	
		Page number: 57	
VITAL SIGNS			
Blood Pressure			
Date	Actual Time	Systolic	Diastolic
29-05-2007	1126	117	69
		Pulse	Respiratory Rate
		66	16
			Oral Temperature
			36.8
			xxx.x
Unit			
C			
Comments			

Section: Oral_Health_Exam	9 of 12	Blank? N	Section Status: Entry Complete
Visit: WEEK 24 (EOS)		Section Date: 29-05-2007	
Entered By: Melissa Zeis		Entry Time: 05-07-2007 16:57:32	
	Last Modification Time: 05-07-2007 17:05:32		
	Page number: 57		
ORAL HEALTH EXAMINATION			
Date			
29-05-2007			
	Procedure	Relevant Findings?*	Findings
	ORAL HEALTH QUESTIONS PERFORMED	NO	
	EVIDENCE OF LEUKOPLAKIA	NO	
	OTHER ORAL KERATOSIS	NO	

Section: Phys_Exam	10 of 12	Blank? N	Section Status: Entry Complete
Visit: WEEK 24 (EOS)		Section Date: 29-05-2007	
Entered By: Melissa Zeis		Entry Time: 05-07-2007 16:57:32	
		Last Modification Time: 18-12-2007 15:37:37	
		Page number: 58	
PHYSICAL EXAMINATION			
Date			
29-05-2007			
Code Number	Code	Relevant Findings?	Findings

# CRF Report for Study E6270229

Patient: 3013  
CRF: Week 24 (Eos)  
Visit: WEEK 24 (EOS)

Site: CDB\_001  
Blank? N  
Visit Date: 29-05-2007

Investigator: CDB\_001  
CRF Page #: 23  
Document #: R147611913

Section: Phys_Exam 10 of 12			
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		11 of 12		Blank? N		Section Status: Entry Complete	
Visit: WEEK 24 (EOS)				Section Date: 29-05-2007			
Entered By: Melissa Zeis				Entry Time: 05-07-2007 16:57:32			
				Last Modification Time: 05-07-2007 17:05:32			
				Page number: 58			
WEIGHT & HEIGHT							
Date	Weight	Unit	Height	Unit			
29-05-2007	57.8	KG	ND				
	xxx.x		xxx.x				

Section: Lab_Eval	12 of 12	Blank? N	Section Status: Entry Complete
Visit: WEEK 24 (EOS)		Section Date: 29-05-2007	
Entered By: Melissa Zeis		Entry Time: 05-07-2007 16:57:32	
		Last Modification Time: 05-07-2007 17:06:20	
		Page number: 59	
Laboratory Evaluations			
Date			
29-05-2007			
Were the scheduled laboratory samples obtained?	YES	No, specify	
Requisition Number 1	N528228		
Requisition Number 2 (if applicable)			
Were there any clinically significant labs?	NO	(Yes, specify below)	
Requisition Number	Test Name	H/L	Lab ID Lab Name

# CRF Report for Study E6270229

Patient: 3013

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? N

Visit Date: 29-05-2007

Entry Time: 05-07-2007 17:06:26

Modification Time: 11-12-2007 13:22:43

Approval Time:

Verification Time:

Investigator: CDB\_001

CRF Page #: 24

Document #: R147616113

CRF Status: Entry Complete

Approver:

Verifier:

Section: Pk_Blood_Biomark	1 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 24 (EOS)		Section Date: 29-05-2007	
Entered By: Melissa Zeis		Entry Time: 05-07-2007 17:06:26	
		Last Modification Time: 11-12-2007 13:22:43	
		Page number: 59	
Blood Sampling For Biomarkers/Chemistry/Hematology (following an overnight fast)			
Date	Actual Time	Comments	
ND	NA		

Section: Expired_Carbon_M	2 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 24 (EOS)		Section Date: 29-05-2007	
Entered By: Melissa Zeis		Entry Time: 05-07-2007 17:06:26	
		Last Modification Time: 11-12-2007 13:07:45	
		Page number: 59	
EXPIRED CARBON MONOXIDE			
Date	Actual Time	ECO Level (ppm)	%COHb
29-05-2007	1155	17	3.3
Comments			

Section: Blood_Sampl_Cohb	3 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 24 (EOS)		Section Date: 29-05-2007	
Entered By: Melissa Zeis		Entry Time: 05-07-2007 17:06:26	
		Last Modification Time: 05-07-2007 17:09:14	
		Page number: 59	
Blood Sampling for %COHb			
Date	Actual Time	Comments	
29-05-2007	ND		

Section: Pre_Bronch_Spir	4 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 24 (EOS)		Section Date: 29-05-2007	
Entered By: Melissa Zeis		Entry Time: 05-07-2007 17:06:26	
		Last Modification Time: 05-07-2007 17:09:14	
		Page number: 60	

# CRF Report for Study E6270229

Patient: 3013

CRF: Week 24-2 (Eos)

Visit: WEEK 24 (EOS)

Site: CDB\_001

Blank? N

Visit Date: 29-05-2007

Investigator: CDB\_001

CRF Page #: 24

Document #: R147616113

Section: Pre_Bronch_Spir		4 of 11					
PRE-BRONCHODILATOR BEST BASELINE SPIROMETRY TEST RESULT							
Actual Time		Testing		FVC			
of FEV1/FVC							
Date	Test	Position	FEV1 L	FEV1 Predicted (%)	FVC L	Predicted (%)	Comments
29-05-2007	1201	STANDI	2.39	90	3.45	102	
		NG					

Section: Proventil_Admin	5 of 11	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)		Section Date: 29-05-2007	
Entered By: Melissa Zeis		Entry Time: 05-07-2007 17:06:26	
		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: 29-05-2007					
Entered By: Melissa Zeis		Entry Time: 05-07-2007 17:06:26					
		Last Modification Time:					
		Page number: 60					
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 24 (EOS)				Section Date: 29-05-2007					
Entered By: Melissa Zeis				Entry Time: 05-07-2007 17:06:26					
				Last Modification Time:					
				Page number: 61					
USED STUDY TOBACCO-HEATING CIGARETTE COLLECTION									
					Number of Study				
					Tobacco-Heating				
Scheduled Collection						Weight of			
						Cigarettes Collected			
						(g)			
						Any Product			
						Deviation?			
						Brand			
						Comments			

# CRF Report for Study E6270229

Patient: 3013

CRF: Week 24-2 (Eos)

Visit: WEEK 24 (EOS)

Site: CDB\_001

Blank? N

Visit Date: 29-05-2007

Investigator: CDB\_001

CRF Page #: 24

Document #: R147616113

Section: Used_Study_Snus	8 of 11	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)		Section Date: 29-05-2007	
Entered By: Melissa Zeis		Entry Time: 05-07-2007 17:06:26	
		Last Modification Time:	
		Page number: 62	

## USED STUDY SNUS COLLECTION

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

Section: Used_Study_Burn	9 of 11	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)		Section Date: 29-05-2007	
Entered By: Melissa Zeis		Entry Time: 05-07-2007 17:06:26	
		Last Modification Time:	
		Page number: 63	

## USED STUDY TOBACCO-BURNING CIGARETTE COLLECTION

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

Section: Used_Butt_Measur	10 of 11	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)		Section Date: 29-05-2007	
Entered By: Melissa Zeis		Entry Time: 05-07-2007 17:06:26	
		Last Modification Time:	
		Page number: 64	

## USUAL STUDY TOBACCO-BURNING CIGARETTE BUTT MEASUREMENT

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

Section: Used_Butt_Measur	11 of 11	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)		Section Date: 29-05-2007	
Entered By: Melissa Zeis		Entry Time: 05-07-2007 17:06:26	
		Last Modification Time:	
		Page number: 65	

## USED STUDY TOBACCO-BURNING CIGARETTE BUTT MEASUREMENT

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

# CRF Report for Study E6270229

Patient: 3013

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? N

Visit Date: 29-05-2007

Entry Time: 05-07-2007 17:09:15

Modification Time: 11-12-2007 13:18:06

Approval Time:

Verification Time:

Investigator: CDB\_001

CRF Page #: 25

Document #: R147617613

CRF Status: Entry Complete

Approver:

Verifier:

Section: Unused_Study_Pro		Blank? N		Section Status: Entry Complete	
Visit: WEEK 24 (EOS)		Section Date: 29-05-2007			
Entered By: Melissa Zeis		Entry Time: 05-07-2007 17:09:15			
		Last Modification Time: 11-12-2007 13:18:06			
		Page number: 65A			

Unused Study Product Returned				Amount Returned	
Date	Actual Time	Product Returned	Flavor	Packs	Individual Cigarettes / pouches
29-05-2007	UNK	SNUS	ORIGINAL	0	0

# CRF Report for Study E6270229

Patient: 3013

CRF: Precon\_Med

Visit: PRECON\_MEDS

Entered By: Christina Breedlove

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB\_001

Blank? N

Visit Date: 18-12-2007

Entry Time: 18-12-2007 15:37:48

Modification Time: 20-12-2007 10:26:35

Approval Time:

Verification Time:

Investigator: CDB\_001

CRF Page #: 26

Document #: R170204013

CRF Status: Entry Complete

Approver:

Verifier:

Section: Pre_Conmed		Blank? N		Section Status: Entry Complete	
Visit: PRECON_MEDS		Section Date: 18-12-2007			
Entered By: Christina Breedlove		Entry Time: 18-12-2007 15:37:48			
		Last Modification Time: 18-12-2007 15:45:53			
		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?									
Dose /									
Seq #	Drug Name	Indication	Dose Unit	Route	Specify	Freq	Specify	Start Date	Stop Date/Ongoing
1	PAXIL	ANXIETY	12.5 MG	PO		QD		19-02-2007	ONGOING
2	TOPAMAX	MIGRAINES	100 MG	PO		QD		00-00-2005	ONGOING
3	XANAX	ANXIETY	.5 MG	PO		PRN		00-00-2002	ONGOING
4	DURATUSS	BRONCHITIS	1 TAB	PO		BID		10-05-2007	20-05-2007
5	CIPRO	BRONCHITIS	750 MG	PO		QD		14-05-2007	21-05-2007
6	ALBUTEROL	BRONCHITIS	2 PUFFS	INH		QID		30-04-2007	21-05-2007
7	AVELOX	BRONCHITIS	500 MG	PO		QD		30-04-2007	07-05-2007

YES



# CRF Report for Study E6270229

Patient: 3013

CRF: AE

Visit: AE

Entered By: Christina Breedlove

Discrepancies: Active

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB\_001

Blank? N

Visit Date: 18-12-2007

Entry Time: 18-12-2007 15:45:54

Modification Time: 11-01-2008 08:35:08

Approval Time:

Verification Time:

Investigator: CDB\_001

CRF Page #: 27

Document #: R170208713

CRF Status: Entry Complete

Approver:

Verifier:

Section: Ae_Med				Blank? N		Section Status: Entry Complete					
Visit: AE				Section Date: 18-12-2007							
Entered By: Christina Breedlove				Entry Time: 18-12-2007 15:45:54							
				Last Modification Time: 11-01-2008 08:35:08							
				Page number: 67							

Adverse Events											
Did the subject experience any adverse events? YES											
Event No.	Adverse Event	Onset		Resolved/Changed		Serious Event?	Severity	Relationship to Product	Relationship to Procedure	Action Taken	Outcome to Date
		Date	Time	Date	Time						
1	HICCUPS	19-04-2007	UNK	22-05-2007	UNK	NO	MILD	PROBABLE	NOT RELATED	NONE	RECOVERED
2	ERUCTION	19-04-2007	UNK	22-05-2007	UNK	NO	MILD	PROBABLE	NOT RELATED	NONE	RECOVERED
3	BRONCHITIS	30-04-2007	UNK	25-05-2007	UNK	NO	MODERATE	NOT RELATED	NOT RELATED	DRUG THERAPY	RECOVERED

# CRF Report for Study E6270229

Patient: 3013

CRF: Ecg\_Unscheduled

Visit: ECG\_UNSCHE

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB\_001

Blank? N

Visit Date: 11-12-2007

Entry Time: 11-12-2007 11:21:07

Modification Time: 11-12-2007 13:04:53

Approval Time:

Verification Time:

Investigator: CDB\_001

CRF Page #: 28

Document #: R169408813

CRF Status: Entry Complete

Approver:

Verifier:

Section: ECG		Blank? N		Section Status: Entry Complete				
Visit: ECG_UNSCHE		Section Date: 11-12-2007						
Entered By: Melissa Zeis		Entry Time: 11-12-2007 11:21:07						
		Last Modification Time: 11-12-2007 13:04:53						
		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
29-05-2007	1150	66	128	92	424	432	ANCS	

# CRF Report for Study E6270229

Patient: 3013

CRF: Lab\_Unscheduled

Visit: LAB\_UNSCHE

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB\_001

Blank? Y

Visit Date: 11-12-2007

Entry Time: 11-12-2007 11:22:11

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB\_001

CRF Page #: 29

Document #: R169409413

CRF Status: Created

Approver:

Verifier:

Section: Lab\_Eval

Blank? Y

Section Status: Created

Visit: LAB\_UNSCHE

Section Date: 11-12-2007

Entered By: Melissa Zeis

Entry Time: 11-12-2007 11:22:11

Last Modification Time:

Page number: 69

## Unscheduled Laboratory Evaluations

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

# CRF Report for Study E6270229

Patient: 3013

CRF: Vital\_Unscheduled

Visit: VITAL\_UNSCHE

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB\_001

Blank? Y

Visit Date: 11-12-2007

Entry Time: 11-12-2007 11:22:19

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB\_001

CRF Page #: 30

Document #: R169409613

CRF Status: Created

Approver:

Verifier:

Section: Vital

Blank? Y

Section Status: Created

Visit: VITAL\_UNSCHE

Section Date: 11-12-2007

Entered By: Melissa Zeis

Entry Time: 11-12-2007 11:22:19

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: 3013

CRF: StdY\_Prdt\_Dis\_Unscheduled

Visit: STDY\_PRDT\_UNSCHE

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB\_001

Blank? Y

Visit Date: 11-12-2007

Entry Time: 11-12-2007 11:22:28

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB\_001

CRF Page #: 31

Document #: R169409713

CRF Status: Created

Approver:

Verifier:

Section: Study\_Prod\_Dispe

Blank? Y

Section Status: Created

Visit: STDY\_PRDT\_UNSCHE

Section Date: 11-12-2007

Entered By: Melissa Zeis

Entry Time: 11-12-2007 11:22:28

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: 3013

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: 11-12-2007

Entry Time: 11-12-2007 11:22:37

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB\_001

CRF Page #: 32

Document #: R169409913

CRF Status: Created

Approver:

Verifier:

Section: Expired\_Carbon\_M

Blank? Y

Section Status: Created

Visit: EXPIRED\_CO2\_UNSC

Section Date: 11-12-2007

Entered By: Melissa Zeis

Entry Time: 11-12-2007 11:22:37

Last Modification Time:

Page number: 72

## UNSCHEDULED EXPIRED CARBON MONOXIDE

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

# CRF Report for Study E6270229

Patient: 3013

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: 11-12-2007

Entry Time: 11-12-2007 11:22:45

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB\_001

CRF Page #: 33

Document #: R169410013

CRF Status: Created

Approver:

Verifier:

Section: Oral\_Health\_Exam

Blank? Y

Section Status: Created

Visit: ORAL\_HEALTH\_UNSC

Section Date: 11-12-2007

Entered By: Melissa Zeis

Entry Time: 11-12-2007 11:22:45

Last Modification Time:

Page number: 73

## UNSCHEDULED ORAL HEALTH EXAMINATION

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

# CRF Report for Study E6270229

Patient: 3013

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: 11-12-2007

Entry Time: 11-12-2007 11:20:51

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB\_001

CRF Page #: 34

Document #: R169408713

CRF Status: Created

Approver:

Verifier:

Section: Pre\_Bronch\_Spir

Blank? Y

Section Status: Created

Visit: SPIRO\_TEST\_UNSCH

Section Date: 11-12-2007

Entered By: Melissa Zeis

Entry Time: 11-12-2007 11:20:51

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: 3013

CRF: Study\_Completion

Visit: STUDY\_COMP

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB\_001

Blank? N

Visit Date: 11-12-2007

Entry Time: 11-12-2007 11:20:12

Modification Time: 11-12-2007 11:20:42

Approval Time:

Verification Time:

Investigator: CDB\_001

CRF Page #: 35

Document #: R169408313

CRF Status: Entry Complete

Approver:

Verifier:

Section: Study\_Comp

Blank? N

Section Status: Entry Complete

Visit: STUDY\_COMP

Section Date: 11-12-2007

Entered By: Melissa Zeis

Entry Time: 11-12-2007 11:20:12

Last Modification Time: 11-12-2007 11:20:42

Page number: 75

## Study Completion

Did the subject complete the study? NO

Date the subject completed OR withdrew from the study: 29-05-2007

Reason for Withdrawal CONSENT

Specify

Investigator Comments

Principal Investigator

Date

23 JAN 2008

**Covance CLS**

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

ACCESSION NO. N527147

Page 1 of 3

## INVESTIGATOR: (B17177)

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

PROTOCOL 6270-229

INVESTIGATOR NO.: 3

RANDOMIZATION NUMBER: (b) (6)

PATIENT INITIALS: (b) (6)

VISIT: 1

## SPONSOR REPORT TO:

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

Screen

COLLECTION TIME: 11:35 DATE: 23-Mar-2007

DATE RECEIVED IN LABORATORY: 24-Mar-2007

DATE REPORTED BY LABORATORY: 27-Mar-2007

SEX: F BIRTHDATE: (b) (6) AGE: 54

SCREENING NUMBER: S3054

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

## CHEMISTRY PANEL

Total Bili	0.3	0.2-1.2 mg/dL
Alk Phos	81	35-123 U/L
ALT (SGPT)	17	6-34 U/L
AST (SGOT)	20	9-34 U/L
GGT	28	4-49 U/L
LDH	158	53-234 U/L
Urea Nitr	14	4-24 mg/dL
Creatinine	0.7	0.4-1.1 mg/dL
Glucose	96	70-115 mg/dL
Uric Acid	3.8	2.5-7.5 mg/dL
Calcium	9.7	8.3-10.6 mg/dL
Phosphorus	3.8	2.2-5.1 mg/dL
Total Prot	7.1	6.1-8.4 g/dL
Albumin	4.0	3.3-4.9 g/dL
Sodium	142	132-147 mEq/L
Potassium	4.1	3.4-5.4 mEq/L
Chloride	105	94-112 mEq/L

13-28-07

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

Qcd AD-09/04/2007

(INV)

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 Daytona Beach, FL 32117

## SPONSOR REPORT TO:

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 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

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DATE REPORTED BY LABORATORY: 27-Mar-2007

SEX: F BIRTHDATE: (b) (6) AGE: 54

SCREENING NUMBER: S3054

Is this Clinically  
 Significant/ Adverse  
 Event?

Yes

No

## HEMATOLOGY &amp; DIFFERENTIAL PANEL

HGB	13.8		11.6-16.4 g/dL
HCT	41		34-48 %
RBC	4.2		4.1-5.6 x10 <sup>6</sup> /uL
MCV	99	H	79-98 fL
MCH	33		26-34 pg
MCHC	33		31-38 g/dL
RDW	13.5		12.0-15.0 %
RBC Morph	Normocytic		
WBC	8.51		3.80-10.70 x10 <sup>3</sup> /uL
Neutrophil	5.25		1.96-7.23 x10 <sup>3</sup> /uL
Lymphocyte	2.57		0.91-4.28 x10 <sup>3</sup> /uL
Monocytes	0.60		0.12-0.92 x10 <sup>3</sup> /uL
Eosinophil	0.07		0.00-0.57 x10 <sup>3</sup> /uL
Basophils	0.03		0.00-0.20 x10 <sup>3</sup> /uL
Neutrophil	61.7		40.5-75.0 %
Lymphocyte	30.1		15.4-48.5 %
Monocytes	7.0		2.6-10.1 %
Eosinophil	0.8		0.0-6.8 %
Basophils	0.3		0.0-2.0 %
Platelets	322		140-400 x10 <sup>3</sup> /uL

*[Handwritten signature]*  
 B. B. n

Investigator Signature:

Date:

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B17177

Qcd L.D. 04/14/2007

(INV)

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ACCESSION NO. N527147

Page 3 of 3

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

PROTOCOL 6270-229

INVESTIGATOR NO.: 3

RANDOMIZATION NUMBER: (b) (6)

PATIENT INITIALS: (b) (6)

VISIT: 1

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DATE REPORTED BY LABORATORY: 27-Mar-2007

SEX: F BIRTHDATE: (b) (6) AGE: 54

SCREENING NUMBER: S3054

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

## URINE MACRO &amp; MICRO PANEL

Color	Colorless	Ref Rng: Colorless or Yellow
Clarity	Clear	Ref Rng: Clear
Spec Grav	1.006	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	

## CELLULAR ELEMENTS

WBC	1	0-12 /HPF
-----	---	-----------

## MICROORGANISMS

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

## MISCELLANEOUS ELEMENTS

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

*Jul Farmer*  
Investigator Signature:

*29 Mar 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

*QCL 10.09/04/2007*  
(INV)

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**LABORATORY REPORT**

ACCESSION NO. N527147

Page 1 of 1

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Covance CRU, Inc.  
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Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 3

RANDOMIZATION NUMBER: (b) (6)

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME: 11:35 DATE: 23-Mar-2007

DATE RECEIVED IN LABORATORY: 24-Mar-2007

DATE REPORTED BY LABORATORY: 27-Mar-2007

SEX: F BIRTHDATE: (b) (6) AGE: 54

SCREENING NUMBER: S3054

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

## TOTAL IRON

Total Iron 65 30-160 ug/dL

## FOLLICLE STIMULATING HORMONE

FSH 54.3

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

*M*  
*7-28-07*

## HEPATITIS A ANTIBODY-IGM

HepA IgM Ab Negative No Ref Rng

*[Signature]*  
Investigator Signature:

*29 MAR 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

*Q'cd 10.09/544/2007*

(INV)

**Covance CLS**

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**LABORATORY REPORT**

ACCESSION NO. N527147

Page 1 of 1

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Daytona Beach, FL 32117

PROTOCOL 6270-229

INVESTIGATOR NO.: 3

RANDOMIZATION NUMBER: (b) (6)

PATIENT INITIALS: (b) (6)

VISIT: 1

## SPONSOR REPORT TO:

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

Screen

COLLECTION TIME: 11:35 DATE: 23-Mar-2007

DATE RECEIVED IN LABORATORY: 24-Mar-2007

DATE REPORTED BY LABORATORY: 27-Mar-2007

SEX: F BIRTHDATE: (b) (6) AGE: 54

SCREENING NUMBER: S3054

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

&lt;1.4

pg/mL

See Inv. Manual

*3-28-07*  
Investigator Signature:*29 MAR 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

*Q.C.A.D. 04/04/2007*

(INV)



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**LABORATORY REPORT**

ACCESSION NO. N527147

Page 1 of 1

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## SPONSOR REPORT TO:

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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: 11:35 DATE: 23-Mar-2007

DATE RECEIVED IN LABORATORY: 24-Mar-2007

DATE REPORTED BY LABORATORY: 27-Mar-2007

SEX: F BIRTHDATE: (b) (6) AGE: 54

SCREENING NUMBER: S3054

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

## HIV 1/HIV 2 ANTIBODY SCREEN

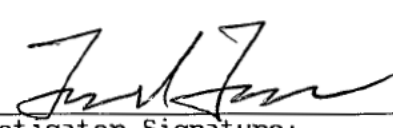
HIV-1/2

Non-Reactive

Reference Range:

Non-Reactive

*3-28-07*

  
Investigator Signature:

*29 MAR 2007*  
Date:

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

B17177

*Q.C. 10-09/04/2007*

(INV)

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**LABORATORY REPORT**

ACCESSION NO. N527147

Page 1 of 1

## INVESTIGATOR: (B17177)

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## 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: (b) (6)

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME: 11:35 DATE: 23-Mar-2007

DATE RECEIVED IN LABORATORY: 24-Mar-2007

DATE REPORTED BY LABORATORY: 27-Mar-2007

SEX: F BIRTHDATE: (b) (6) AGE: 54

SCREENING NUMBER: S3054

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

## HEPATITIS B CORE ANTIBODY-IGM

Hep Bc IgM Negative Ref Rng: Negative

*3.28-07*

*Jul Jm*  
Investigator Signature:

*29 MAR 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

*Qce 10.09/544/2007*

(INV)



**Covance CLS**

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

**LABORATORY REPORT**

ACCESSION NO. N527147

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: (b) (6)

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME: 11:35 DATE: 23-Mar-2007

DATE RECEIVED IN LABORATORY: 24-Mar-2007

DATE REPORTED BY LABORATORY: 27-Mar-2007

SEX: F BIRTHDATE: (b) (6) AGE: 54

SCREENING NUMBER: S3054

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

*R  
3-28-07*

  
Investigator Signature:

*29 MAR 07*  
Date:

B17177

*Q ce 10-09/14/2007*

(INV)

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**LABORATORY REPORT**

ACCESSION NO. N528158

Page 1 of 1

## INVESTIGATOR: (B17177)

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c/o Melissa Zeis  
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1900 Mason Ave  
Daytona Beach, FL 32117

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

PROTOCOL 6270-229

INVESTIGATOR NO.: 3

RANDOMIZATION NUMBER: R3013

PATIENT INITIALS: (b) (6)

VISIT: 24 HR UR

24 Hr Urine Collection

COLLECTION TIME: 15:45 DATE: 17-Apr-2007

DATE RECEIVED IN LABORATORY: 20-Apr-2007

DATE REPORTED BY LABORATORY: 20-Apr-2007

SEX: F BIRTHDATE: (b) (6) AGE: 54

SCREENING NUMBER: S3054

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

## URINE CREATININE, 24 HR

U24h Creat 974

UAlq24Crea 28.4

600-1600 mg/24hr

mg/dL No Ref Rng

## ELAPSED DATE AND TIME, 24HR

Elpsd D&amp;T 1440

min

*23 min*

## 24 HR COLLECTION INFORMATION

Start Date 17-Apr-2007

Start Time 15:45

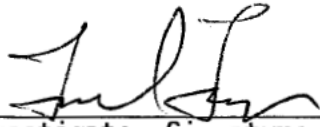
Stop Date 18-Apr-2007

Stop Time 15:45

## TOTAL 24HR URINE VOLUME

Total Vol. 3430

mL

*Rid m3  
27/APR/2007*  
Investigator Signature:*23 APR 2007*  
Date:

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ACCESSION NO. N527197

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Medical Director  
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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: 2

Week 0

COLLECTION TIME: 07:06 DATE: 18-Apr-2007

DATE RECEIVED IN LABORATORY: 19-Apr-2007

DATE REPORTED BY LABORATORY: 19-Apr-2007

SEX: F BIRTHDATE: (b) (6) AGE: 54

SCREENING NUMBER: S3054

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

## CHEMISTRY PANEL

Total Bili	0.3	0.2-1.2 mg/dL
Alk Phos	100	35-123 U/L
ALT (SGPT)	25	6-34 U/L
AST (SGOT)	25	9-34 U/L
GGT	31	4-49 U/L
LDH	175	53-234 U/L
Urea Nitr	11	4-24 mg/dL
Creatinine	0.9	0.4-1.1 mg/dL
Glucose	100	70-115 mg/dL
Uric Acid	3.6	2.5-7.5 mg/dL
Calcium	10.2	8.3-10.6 mg/dL
Phosphorus	4.4	2.2-5.1 mg/dL
Total Prot	8.0	6.1-8.4 g/dL
Albumin	4.5	3.3-4.9 g/dL
Sodium	139	132-147 mEq/L
Potassium	3.9	3.4-5.4 mEq/L
Chloride	101	94-112 mEq/L

*23 APR 2007**Rec'd m3 27 APR 2007*

Investigator Signature:

*23 APR 2007*

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SCREENING NUMBER: S3054

Is this Clinically  
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Event?

Yes

No

**HEMATOLOGY& DIFFERENTIAL PANEL**


HGB	15.0	11.6-16.4 g/dL
HCT	47	34-48 %
RBC	4.8	4.1-5.6x10 <sup>6</sup> /uL
MCV	98	79-98 fL
MCH	32	26-34 pg
MCHC	32	31-38 g/dL
RDW	13.6	12.0-15.0 %
RBC Morph	Normocytic	
WBC	11.70 H	3.80-10.70 x10 <sup>3</sup> /uL
Neutrophil	6.80	1.96-7.23 x10 <sup>3</sup> /uL
Lymphocyte	3.85	0.91-4.28 x10 <sup>3</sup> /uL
Monocytes	0.89	0.12-0.92 x10 <sup>3</sup> /uL
Eosinophil	0.11	0.00-0.57 x10 <sup>3</sup> /uL
Basophils	0.04	0.00-0.20 x10 <sup>3</sup> /uL
Neutrophil	58.2	40.5-75.0 %
Lymphocyte	32.9	15.4-48.5 %
Monocytes	7.6	2.6-10.1 %
Eosinophil	1.0	0.0-6.8 %
Basophils	0.4	0.0-2.0 %
Platelets	325	140-400 x10 <sup>3</sup> /uL

[ ]

[ ]

23 APR 2007

Rid  
mz  
23 APR 2007



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23 APR 2007

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SCREENING NUMBER: S3054

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Significant/ Adverse  
Event?

Yes

No

## HOMOCYSTEINE

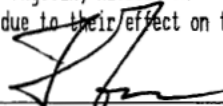
\*1 HCY

13.14

3.36-20.44 umol/L

*23 Apr 2007**R. J. J. 27/04/2007*

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.

  
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Significant/ Adverse  
Event?

Yes

No

## FIBRINOGEN

Fibrinogen 406 H 200-400 mg/dL

[ ]

[X]

*23 APR 2007*

*Plat M3  
27 APR 2007*

*[Signature]*

Investigator Signature:

*23 APR 2007*

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SCREENING NUMBER: S3054

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

URINE CREATININE, SPOT

Rnd Ur Crt 12

mg/dL No Ref Rng

*23 APR 2007*

*Rnd  
M2 27/04/2007*

*[Signature]*

Investigator Signature:

*23 APR 2007*  
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SEX: F BIRTHDATE: (b) (6) AGE: 54

SCREENING NUMBER: S3054

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

sICAM-1

sICAM-1

To follow

*Handwritten signature*  
22 APR 2007

*Handwritten signature*  
27 APR 2007

*Handwritten signature*

Investigator Signature:

*Handwritten signature*  
23 APR 2007

Date:

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PROTOCOL 6270-229

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RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 07:06 DATE: 18-Apr-2007

DATE RECEIVED IN LABORATORY: 19-Apr-2007

DATE REPORTED BY LABORATORY: 19-Apr-2007

SEX: F BIRTHDATE: (b) (6)

AGE: 54

SCREENING NUMBER: S3054


Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

RBC CELL WASHING (4-ABP-HB)

Wash/Store Completed

*23 APR 2007**Rid  
M3  
27 APR 2007*

Investigator Signature:

*23 APR 2007*  
Date:

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PROTOCOL 6270-229

INVESTIGATOR NO.: 3

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 07:06 DATE: 18-Apr-2007

DATE RECEIVED IN LABORATORY: 19-Apr-2007

DATE REPORTED BY LABORATORY: 19-Apr-2007

SEX: F BIRTHDATE: (b) (6) AGE: 54

SCREENING NUMBER: S3054

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

HAS PATIENT FASTED 8 HOURS?

Fasted?

Yes

*Frank Farmer**Rid  
m3  
27 APR 2007**FL*

Investigator Signature:

*23 APR 2007*

Date:

B17177

(INV)

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RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

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DATE RECEIVED IN LABORATORY: 19-Apr-2007

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SEX: F BIRTHDATE: (b) (6) AGE: 54

SCREENING NUMBER: S3054

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

## HEMOGLOBIN A1C

Hgb A1c

5.5

Normals:

4.3-6.1%

Stable Diabetics:

4.2-11.2%

23 APR 2007

Riv  
M3 27 Apr 2007



Investigator Signature:

23 APR 2007

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INVESTIGATOR NO.: 3

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

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SEX: F BIRTHDATE: (b) (6) AGE: 54

SCREENING NUMBER: S3054

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

**LIPID PANEL**

Triglycer	197		52-262 mg/dL
Cholest	300	H	171-291 mg/dL
HDL Dex-S	67		37-91 mg/dL
LDL Chol	194		88-201 mg/dL

[ ]

[ / ]

23 APR 2007

River  
11/3 27/10/2007

Investigator Signature:

Date:

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INVESTIGATOR NO.: 3

RANDOMIZATION NUMBER: R3013

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 07:06 DATE: 18-Apr-2007

DATE RECEIVED IN LABORATORY: 19-Apr-2007

DATE REPORTED BY LABORATORY: 26-Apr-2007

SEX: F BIRTHDATE: (b) (6) AGE: 54

SCREENING NUMBER: S3054

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

sICAM-1

sICAM-1

354

H

115-306 ng/mL

[ ]

[x]

*Farmer*

*Lud*  
*27 APR 2007 m3*

*Frank Farmer*

Investigator Signature:

*27 APR 2007*

Date:

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RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 07:06 DATE: 18-Apr-2007

DATE RECEIVED IN LABORATORY: 19-Apr-2007

DATE REPORTED BY LABORATORY: 20-Apr-2007

SEX: F BIRTHDATE: (b) (6) AGE: 54

SCREENING NUMBER: S3054

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

## TOTAL IRON

Total Iron 49 30-160 ug/dL

## C-REACTIVE PROTEIN


CRP-HS 0.529 H <=0.287 mg/dL

## CARBOXYHEMOGLOBIN

Carboxyhem 6.5 % saturation  
No Ref Rng

*23 Apr 2007*

*Rid MZ 27 APR 2007*

  
Investigator Signature:

*23 APR 2007*  
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VISIT: 2

Week 0

COLLECTION TIME: 07:06 DATE: 18-Apr-2007

DATE RECEIVED IN LABORATORY: 19-Apr-2007

DATE REPORTED BY LABORATORY: 19-Apr-2007

SEX: F BIRTHDATE: (b) (6) AGE: 54

SCREENING NUMBER: S3054

Is this Clinically  
Significant/ Adverse  
Event?

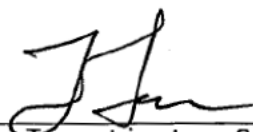
Yes

No

OXIDIZED LDL

OxidizeLDL

To follow

*23 APR 2007**Rud  
143  
27 APR 2007*

Investigator Signature:

*23 APR 2007*

Date:

H(High) or L(Low)=Values above or below reference range.

Testing performed by: Pacific Biometrics

220 West Harrison Street; Seattle, WA 98119

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. N527197

Page 1 of 1

**INVESTIGATOR: (B20476)**

Frank Farmer, Jr., M.D.

c/o Deborah Jacobsen

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: R3013

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 07:06 DATE: 18-Apr-2007

DATE RECEIVED IN LABORATORY: 19-Apr-2007

DATE REPORTED BY LABORATORY: 21-Jan-2008

SEX: F BIRTHDATE: (b) (6) AGE: 54

SCREENING NUMBER: S3054

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

OXIDIZED LDL

OxidizeLDL

120

H

30-110 U/L

☐☒*P 22 Jan 2008**IF*

Investigator Signature:

*23 JAN 2008*

Date:

H(High) or L(Low)=Values above or below reference range.

Testing performed by: Pacific Biometrics

220 West Harrison Street; Seattle, WA 98119

B20476

(INV)

**Covance CLS**

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**LABORATORY REPORT**

ACCESSION NO. N527275

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: R3013

PATIENT INITIALS: (b) (6)

VISIT: 4

Week 2

COLLECTION TIME: 13:35 DATE: 03-May-2007

DATE RECEIVED IN LABORATORY: 04-May-2007

DATE REPORTED BY LABORATORY: 07-May-2007

SEX: F BIRTHDATE: (b) (6) AGE: 54

SCREENING NUMBER: S3054

Is this Clinically  
Significant/ Adverse  
Event?

Yes


No

## CARBOXYHEMOGLOBIN

Carboxyhem 1.0

% saturation

No Ref Rng

  
Investigator Signature:09 MAY 2007  
Date:

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

B17177

Qcd A.O. 09/Jun/2007

(INV)

THE DEVELOPMENT SERVICES COMPANY

1900 Mason Ave. Daytona Beach, Fl. 32117

#### POINT OF CARE TEST REQUISITION AND RESULTS

Date Collected: 29 MAY 2007 Time Collected: 1656 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 checked="" type="checkbox"/> Urine Pregnancy Test Brand: Sure-Vue	5100705	June 07	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> positive <input checked="" type="checkbox"/> negative	1307	JA

☐ **Urine Dipstick (Reagent Strip)**

Brand: \_\_\_\_\_ Lot# \_\_\_\_\_ Exp. Date: \_\_\_\_\_ Quality Control Performed? ☐ Yes ☒ No

Glucose:	Bilirubin	Ketones	Sp. Gravity	Blood	pH	Protein
			1.0 ———			
Urobilinogen	Nitrate	Leukocytes				

Time of Results (24 hour clock): \_\_\_\_\_ Staff Initials: \_\_\_\_\_

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 \_\_\_\_\_

File Requisition and Results Form in the POC Test Results Binder

Rev'd by 1B15 JUN 2007

**Covance CLS**

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Tel. +1 (800) 327 7270

**LABORATORY REPORT**

ACCESSION NO. N528228

Page 1 of 1

## INVESTIGATOR: (B20476)

Frank Farmer, Jr., M.D.  
c/o Deborah Jacobsen  
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: R3013

PATIENT INITIALS: (b) (6)

VISIT: 15

Week 24/Early Term

COLLECTION TIME: 10:59 DATE: 29-May-2007

DATE RECEIVED IN LABORATORY: 30-May-2007

DATE REPORTED BY LABORATORY: 27-Jul-2007

SEX: F BIRTHDATE: (b) (6) AGE: 54

SCREENING NUMBER: S3054

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

FIBRINOGEN - See Note #1

*31 Jul 2007*

Note #1 - No specimen received

*[Signature]*  
Investigator Signature:

*01 Aug 2007*  
Date:

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

B20476

(INV)



**Covance CLS**

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Tel. +1 (800) 327 7270  
**LABORATORY REPORT**

ACCESSION NO. N528228

Page 1 of 1

**INVESTIGATOR: (B20476)**

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

**SPONSOR REPORT TO:**

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Medical Director  
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3402 Kinsman Boulevard  
Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 3

RANDOMIZATION NUMBER: R3013

PATIENT INITIALS: (b) (6)

VISIT: 15

Week 24/Early Term

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SEX: F BIRTHDATE: (b) (6) AGE: 54

SCREENING NUMBER: S3054

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

sICAM-1 - See Note #1

*31/Jul/2007*

Note #1 - No specimen received

*[Signature]*  
Investigator Signature:

*01 AUG 2007*  
Date:

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B20476

(INV)

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ACCESSION NO. N528228

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VISIT: 15

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SEX: F BIRTHDATE: (b) (6) AGE: 54

SCREENING NUMBER: S3054

Is this Clinically  
Significant/ Adverse  
Event?

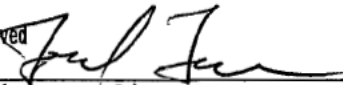
Yes

No

OXIDIZED LDL - See Note #1

*171 Jul 2007*

Note #1 - No specimen received

  
Investigator Signature:*01 Aug 2007*  
Date:

H(High) or L(Low)-Values above or below reference range.  
Testing performed by: Pacific Biometrics  
220 West Harrison Street; Seattle, WA 98119

B20476

(INV)

**Covance CLS**

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**LABORATORY REPORT**

ACCESSION NO. N528228

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: R3013

PATIENT INITIALS: (b) (6)

VISIT: 15

Week 24/Early Term

COLLECTION TIME: 10:59 DATE: 29-May-2007

DATE RECEIVED IN LABORATORY: 30-May-2007

DATE REPORTED BY LABORATORY: 30-May-2007

SEX: F BIRTHDATE: (b) (6) AGE: 54

SCREENING NUMBER: S3054

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

## CHEMISTRY PANEL

Total Bili	0.2	0.2-1.2 mg/dL
Alk Phos	109	35-123 U/L
ALT (SGPT)	16	6-34 U/L
AST (SGOT)	23	9-34 U/L
GGT	25	4-49 U/L
LDH	175	53-234 U/L
Urea Nitr	15	4-24 mg/dL
Creatinine	0.8	0.4-1.1 mg/dL
Glucose	102	70-115 mg/dL
Uric Acid	3.2	2.5-7.5 mg/dL
Calcium	9.8	8.3-10.6 mg/dL
Phosphorus	4.2	2.2-5.1 mg/dL
Total Prot	7.9	6.1-8.4 g/dL
Albumin	4.4	3.3-4.9 g/dL
Sodium	140	132-147 mEq/L
Potassium	4.2	3.4-5.4 mEq/L
Chloride	102	94-112 mEq/L

Investigator Signature:

09 JUN 2007  
Date:

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T=Telephoned P="Panic" EX=Exclusion-as specified by the sponsor

B17177

Ged ASD 09/JUN/2007

(INV)

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**LABORATORY REPORT**

ACCESSION NO. N528228

Page 2 of 3

**INVESTIGATOR: (B17177)**

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Covance-Daytona  
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PROTOCOL 6270-229

INVESTIGATOR NO.: 3

RANDOMIZATION NUMBER: R3013

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SCREENING NUMBER: S3054

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

**HEMATOLOGY& DIFFERENTIAL PANEL**

HGB	16.2		11.6-16.4 g/dL
HCT	49	H	34-48 %
RBC	5.0		4.1-5.6x10 <sup>6</sup> /uL
MCV	97		79-98 fL
MCH	32		26-34 pg
MCHC	33		31-38 g/dL
RDW	13.4		12.0-15.0 %
RBC Morph	Normocytic		
WBC	7.87		3.80-10.70 x10 <sup>3</sup> /uL
Neutrophil	4.25		1.96-7.23 x10 <sup>3</sup> /uL
Lymphocyte	2.65		0.91-4.28 x10 <sup>3</sup> /uL
Monocytes	0.83		0.12-0.92 x10 <sup>3</sup> /uL
Eosinophil	0.10		0.00-0.57 x10 <sup>3</sup> /uL
Basophils	0.04		0.00-0.20 x10 <sup>3</sup> /uL
Neutrophil	54.0		40.5-75.0 %
Lymphocyte	33.8		15.4-48.5 %
Monocytes	10.5	H	2.6-10.1 %
Eosinophil	1.3		0.0-6.8 %
Basophils	0.5		0.0-2.0 %
Platelets	332		140-400 x10 <sup>3</sup> /uL

[ ]

[x]

[ ]

[x]

Investigator Signature:

04 JUN 2007  
Date:

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

T=Telephoned P="Panic" EX=Exclusion-as specified by the sponsor

B17177

Qcd 10.09/04/2007  
(INV)



**Covance CLS**

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Tel. +1 (800) 327 7270

**LABORATORY REPORT**

ACCESSION NO. N528228

Page 3 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: R3013

PATIENT INITIALS: (b) (6)

VISIT: 15

Week 24/Early Term

COLLECTION TIME: 10:59 DATE: 29-May-2007

DATE RECEIVED IN LABORATORY: 30-May-2007

DATE REPORTED BY LABORATORY: 30-May-2007

SEX: F BIRTHDATE: (b) (6) AGE: 54

SCREENING NUMBER: S3054

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

## URINE MACRO &amp; MICRO PANEL

Color	Colorless	Ref Rng: Colorless or Yellow
Clarity	Clear	Ref Rng: Clear
Spec Grav	1.006	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	+1 H	Ref Rng: Negative
Microscop	Positive	

[ ]

[x]

## CELLULAR ELEMENTS

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

## MISCELLANEOUS ELEMENTS

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

*[Signature]*  
Investigator Signature:

*04 JUN 2007*  
Date:

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T=Telephoned P="Panic" EX=Exclusion-as specified by the sponsor

B17177

(INV)

*Qcd 20-09/Jun/2007*

**Covance CLS**

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**LABORATORY REPORT**

ACCESSION NO. N528228

Page 1 of 1

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Covance-Daytona  
1900 Mason Ave  
Daytona Beach, FL 32117

## SPONSOR REPORT TO:

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Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 3

RANDOMIZATION NUMBER: R3013

PATIENT INITIALS: (b) (6)

VISIT: 15

Week 24/Early Term

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SEX: F BIRTHDATE: (b) (6) AGE: 54

SCREENING NUMBER: S3054

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

FIBRINOGEN - See Note #1

Fibrinogen Awaiting specimen arrival

Note #1 - Specimen not submitted; please ship or testing will be canceled.

*John J. Farmer, Jr.*  
Investigator Signature:

*04 JUN 2007*  
Date:

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

B17177

*QCE 10-09/04/2007*

(INV)

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**LABORATORY REPORT**

ACCESSION NO. N528228

Page 1 of 1

**INVESTIGATOR: (B17177)**

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c/o Melissa Zeis

Covance-Daytona

1900 Mason Ave

Daytona Beach, FL 32117

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Medical Director

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Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 3

RANDOMIZATION NUMBER: R3013

PATIENT INITIALS: (b) (6)

VISIT: 15

Week 24/Early Term

COLLECTION TIME: 10:59 DATE: 29-May-2007

DATE RECEIVED IN LABORATORY: 30-May-2007

DATE REPORTED BY LABORATORY: 30-May-2007

SEX: F BIRTHDATE: (b) (6) AGE: 54

SCREENING NUMBER: S3054

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

HOMOCYSTEINE - See Note #1

Note #1 - No specimen received

*[Signature]*  
Investigator Signature:

*04 JUN 2007*  
Date:

H(High) or L(Low)-Values above or below Covance CLS reference range

T=Telephoned P="Panic" EX=Exclusion-as specified by the sponsor

B17177

*QCR 10.09/544/2007*

(INV)

**Covance CLS**

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8211 SciCor Drive - Indianapolis, IN 46214-2985  
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**LABORATORY REPORT**

ACCESSION NO. N528228

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.  
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Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 3

RANDOMIZATION NUMBER: R3013

PATIENT INITIALS: (b) (6)

VISIT: 15

Week 24/Early Term

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SEX: F BIRTHDATE: (b) (6) AGE: 54

SCREENING NUMBER: S3054

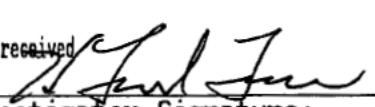
Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

URINE CREATININE, SPOT - See Note #1

Note #1 - No specimen received

  
Investigator Signature:

04 JUN 2007  
Date:

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

B17177

Q'ce AD-09/04/2007

(INV)

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Daytona Beach, FL 32117

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PROTOCOL 6270-229

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SCREENING NUMBER: S3054

Is this Clinically  
Significant/ Adverse  
Event?


Yes

No

sICAM-1 - See Note #1

sICAM-1 Awaiting specimen arrival

Note #1 - Specimen not submitted; please ship or testing will be canceled.

  
Investigator Signature:

*04 Jun 2007*  
Date:

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

B17177

*QCE SD 09/04/2007*

(INV)

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Medical Director

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PATIENT INITIALS: (b) (6)

VISIT: 15

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DATE REPORTED BY LABORATORY: 30-May-2007

SEX: F BIRTHDATE: (b) (6) AGE: 54

SCREENING NUMBER: S3054


Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

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

Note #1 - No specimen received

  
Investigator Signature:04 JUN 2007  
Date:

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

B17177

Ocd A.O. 09/14/2007

(INV)



**Covance CLS**

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

**LABORATORY REPORT**

ACCESSION NO. N528228

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: R3013

PATIENT INITIALS: (b) (6)

VISIT: 15

Week 24/Early Term

COLLECTION TIME: 10:59 DATE: 29-May-2007

DATE RECEIVED IN LABORATORY: 30-May-2007

DATE REPORTED BY LABORATORY: 30-May-2007

SEX: F BIRTHDATE: (b) (6) AGE: 54

SCREENING NUMBER: S3054

Is this Clinically  
Significant/ Adverse  
Event?

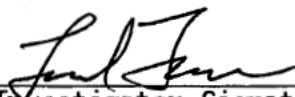
Yes

No

HAS PATIENT FASTED 8 HOURS?

Fasted?

Yes

  
Investigator Signature:

04 JUN 2007  
Date:

B17177

Q'ce A.D. 09/15/2007

(INV)

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SCREENING NUMBER: S3054

Is this Clinically  
Significant/ Adverse  
Event?


Yes

No

OXIDIZED LDL - See Note #1

OxidizeLDL Awaiting specimen arrival

Note #1 - Specimen not submitted; please ship or testing will be canceled.

  
Investigator Signature:

04 JUN 2007  
Date:

H(High) or L(Low)-Values above or below reference range.

Testing performed by: Pacific Biometrics

220 West Harrison Street; Seattle, WA 98119

B17177

(INV)

Qcd 10.09/JUN 2007

**Covance CLS**



**Covance CLS**

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RANDOMIZATION NUMBER: R3013

PATIENT INITIALS: (b) (6)

VISIT: 15

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COLLECTION TIME: 10:59 DATE: 29-May-2007

DATE RECEIVED IN LABORATORY: 30-May-2007

DATE REPORTED BY LABORATORY: 30-May-2007

SEX: F BIRTHDATE: [REDACTED] AGE: 54

SCREENING NUMBER: S3054

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

## HEMOGLOBIN A1C

Hgb A1c

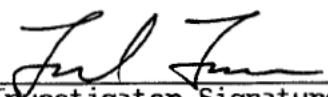
5.5

Normals:

4.3-6.1%

Stable Diabetics:

4.2-11.2%

  
Investigator Signature:

04JUN 2007  
Date:

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B17177

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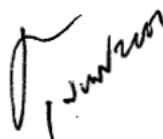
Is this Clinically  
Significant/ Adverse  
Event?

Yes

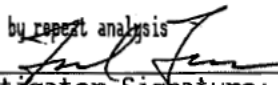
No

**LIPID PANEL**

Triglycer	99	52-262 mg/dL
Cholest	265	171-291 mg/dL
#1 HDL Dex-S	91	37-91 mg/dL
LDL Chol	154	88-201 mg/dL



Note #1 - Result verified by repeat analysis

Investigator Signature: 04 JUN 2007  
Date:

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T-Telephoned P-"Panic" EX-Exclusion-as specified by the sponsor

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SCREENING NUMBER: S3054

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

TOTAL IRON

Total Iron 52

30-160 ug/dL

C-REACTIVE PROTEIN - See Note #1

CARBOXYHEMOGLOBIN

Carboxyhem 5.6

% saturation

No Ref Rng

*Handwritten signature*

Note #1 - No specimen received

*Handwritten signature*  
Investigator Signature:*04 JUN 2007*  
Date:

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T=Telephoned P="Panic" EX=Exclusion-as specified by the sponsor

B17177

*Q.C. 10-09/04/2007*

(INV)