

# CRF Report for Study E6270229

Report run by Sherepta Mcleod at 07-12-2007 11:30:02

## Report Parameters

Site: CB\_001

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: 1002

Ending patient: 1002

## 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)

Page ID: D11965513

/ Covance No. 6270-229

Data Clarification Form

To: Covance CRU Boise  
Investigator: Bryan Pogue  
Date: 15-APR-2008

Patient#: 1002  
Patient Initials:  
Reviewer: Dawn Taylor

Form Name / Visit Name	Page # Date	Questions/Comments	Resolution
Unused Study Product Returned WEEK 24 (EOS) Disc ID: 1384373813 Type: MANUAL	25 13MAR07 Closed: N	W24 'unused study product returned' provides a data line for frost flavor snus, however frost flavor was not dispensed at the last visit.	<input checked="" type="checkbox"/> Delete frost data line <input type="checkbox"/> Other: _____

verify  
to PDL  
Wm2  
042708

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.

*Bryan C. Pogue, M.D.*

Authorized Personnel Signature

APR 15 2008

Date

Page ID: D11965513

/ Covance No. 6270-229

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To: Covance CRU Boise  
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13  
0042008

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*Bryan C. Pogue, M.D.*

Authorized Personnel Signature

APR 18 2008

Date

Page 1 of 1

DCF ID: 52332513

Revision #: 0

Page ID: D11320413

/ Covance No. 6270-229

Data Clarification Form

To: Covance CRU Boise  
Investigator: Bryan Pogue  
Date: 29-JAN-2008

Patient#: 1002  
Patient Initials:  
Reviewer: Dawn Taylor

Form Name / Visit Name	Page # Date	Questions/Comments	Resolution
Study Completion STUDY_COMP Disc ID: 1294826513 Type: MANUAL	35 13MAR07 Closed: N	Reason subject withdrew is 'Consent Withdrawn', with a Specify comment provided. CRF completion does not allow for Specify comments associated with 'Consent Withdrawn'. Please confirm deletion of 'Moved out of town' comment.	<input checked="" type="checkbox"/> Delete Specify comment <input type="checkbox"/> Maintain Specify comment

Joe  
18 Feb 08

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

Page 1 of 1

DCF ID: 48936013

Revision #: 0



Page ID: D11183513

/ Covance No. 6270-229

Data Clarification Form

To: Covance CRU Boise  
Investigator: Bryan Pogue  
Date: 11-JAN-2008

Patient#: 1002  
Patient Initials:  
Reviewer: Dawn Taylor

Form Name / Visit Name	Page # Date	Questions/Comments	Resolution
24-Hour Urine Collection WEEK 0 (BASELINE) Disc ID: 1264588813 Type: MANUAL	5 13FEB07 Closed: N	W0 0-24H Urine Collection notes a stop time of 15:09 and a volume of 1810. Lab documents note a stop time of 15:07 and a volume of 1800. Please verify these values.	Stop Time <input checked="" type="checkbox"/> 15:09 Updated lab req attached <input type="checkbox"/> 15:07 Volume <input checked="" type="checkbox"/> 1810 Updated lab req attached <input type="checkbox"/> 1800

*De  
2/2/08*

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.

*Bryan C. Pogue, M.D.*

Authorized Personnel Signature

*JAN 16 2008*

Date

## Data Clarification Form

To: Covance CRU Boise  
Investigator: Bryan Pogue  
Date: 11-JAN-2008

Patient#: 1002  
Patient Initials:  
Reviewer: Dawn Taylor

Form Name / Visit Name	Page # Date	Questions/Comments	Resolution
24-Hour Urine Collection WEEK 24 (EOS) <b>Disc ID:</b> 1265098213 <b>Type:</b> MANUAL	23 13MAR07 <b>Closed:</b> N	Please address the following regarding the W24 (EOS) 24-Hour Urine Collection data:  1-Spot collection notes a Stop date/time of 13-03-2007/UNK, and a volume of UNK. For consistency of spot urine collection reporting, please confirm these fields should be updated to 'NA'.  2-0H-24 currently notes a Start/Stop date of 13-03-2007, however remaining fields are populated with 'ND'. Please verify if this collection was done and update fields appropriately.	1- <input checked="" type="checkbox"/> Stop date/time and a volume = 'NA' [ ] Other: _____  2- <input checked="" type="checkbox"/> 0H-24 collection=ND [ ] 0H-24H collection=Done Start date/time=_____/_____ Stop date/time=_____/_____ Volume=_____

*23 Jan 08*

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.

*Bryan C. Pogue, M.D.*

Authorized Personnel Signature

*JAN 16 2008*

Date

## Data Clarification Form

To: Covance CRU Boise  
Investigator: Bryan Pogue  
Date: 11-JAN-2008

Patient#: 1002  
Patient Initials:  
Reviewer: Dawn Taylor

Form Name / Visit Name	Page # Date	Questions/Comments	Resolution
Demography SCREENING Disc ID: 1265213213 Type: MANUAL	2 31JAN07 Closed: N	Please provide the Screening weight value to one decimal.	<input checked="" type="checkbox"/> 136.0 <input type="checkbox"/> _____
Laboratory Evaluation WEEK 24 (EOS) Disc ID: 1265311613 Type: MANUAL HEADER	13MAR07 Closed: N	W24 Lipid Panel and Oxidized LDL result laboratory documents were not provided. Please forward with this dcf.	<input checked="" type="checkbox"/> Lab Documents attached tests not done <input type="checkbox"/> Results not available

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.

*Bryan C. Pogue, M.D.*

Authorized Personnel Signature

JAN 16 2008

Date

**Covance CLS**

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

**LABORATORY REPORT**

ACCESSION NO. N527977

Page 1 of 1

INVESTIGATOR: (B17173)

Bryan Pogue, M.D.  
c/o Sherepta Mcleod  
6565 W Emerald St.  
Boise, ID United States 83704

PROTOCOL 6270-229

INVESTIGATOR NO.: 1

RANDOMIZATION NUMBER: R1002

PATIENT INITIALS: (b) (6)

VISIT: 15

SPONSOR REPORT TO:

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

Week 24/Early Term

COLLECTION TIME: 11:30 DATE: 13-Mar-2007

DATE RECEIVED IN LABORATORY: 14-Mar-2007

DATE REPORTED BY LABORATORY: 14-Mar-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S1008

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

LIPID PANEL - See Note #1

Note #1 - No specimen received

*Bryan C. Pogue, M.D.*Investigator Signature: *[Signature]* MAR 16 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

B17173

(INV)

**Covance CLS**

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

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**LABORATORY REPORT**

ACCESSION NO. N527977

Page 1 of 1

INVESTIGATOR: (B17173)

Bryan Pogue, M.D.  
c/o Sherepta Mcleod  
6565 W Emerald St.  
Boise, ID United States 83704

PROTOCOL 6270-229

INVESTIGATOR NO.: 1

RANDOMIZATION NUMBER: R1002

PATIENT INITIALS: (b) (6)

VISIT: 15

Week 24/Early Term

SPONSOR REPORT TO:

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

COLLECTION TIME: 11:30 DATE: 13-Mar-2007

DATE RECEIVED IN LABORATORY: 14-Mar-2007

DATE REPORTED BY LABORATORY: 14-May-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S1008

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

OXIDIZED LDL - See Note #1

*Bryan C. Pogue, M.D.*

Note #1 - No specimen received

JAN 16 2008

Investigator Signature:

Date:

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

B17173

(INV)

Page ID: D11183813

/ Covance No. 6270-229

Data Clarification Form

To: Covance CRU Boise  
Investigator: Bryan Pogue  
Date: 11-JAN-2008

Patient#: 1002  
Patient Initials:  
Reviewer: Dawn Taylor

Form Name / Visit Name	Page # Date	Questions/Comments	Resolution
Weight & Height WEEK 0 (BASELINE) Disc ID: 1265296513 Type: MANUAL	5 13FEB07 Closed: N	Please provide the W0 and W24 height value to one decimal.	W0 [ ] 170.0 [X] 170.0 W24 [ ] 170.0 [X] 170.0 NOT REPEATED

23 Jan 08

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Bryan C. Pogue, M.D.

Authorized Personnel Signature

JAN 16 2008

Date

# CRF Report for Study E6270229

Patient: 1002  
CRF: Header\_Page  
Visit: SCREENING  
Entered By: Sherepta Mcleod  
Discrepancies: None  
Approval Status: Not Approved  
Verification: Not Verified  
Comment:

Site: CB\_001  
Blank? N  
Visit Date: 31-01-2007  
Entry Time: 22-04-2007 15:12:06  
Modification Time: 22-04-2007 15:36:45  
Approval Time:  
Verification Time:

Investigator: C2474\_138  
CRF Page #: 1  
Document #: R138624713  
CRF Status: Entry Complete  
Approver:  
Verifier:

Section: Header_Info	Blank? N	Section Status: Entry Complete
Visit: SCREENING	Section Date: 31-01-2007	
Entered By: Sherepta Mcleod	Entry Time: 22-04-2007 15:12:06	
	Last Modification Time: 22-04-2007 15:36:45	
	Page number: 1	

RDC CASE REPORT FORM		SMOKER
Sponsor Name	Investigator	Site
RJ REYNOLDS TOBACCO COMPANY	BRYAN POGUE	1
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: 1002	Site: CB_001	Investigator: C2474_138
CRF: Screening	Blank? N	CRF Page #: 2
Visit: SCREENING	Visit Date: 31-01-2007	Document #: R138624813
Entered By: Sherepta Mcleod	Entry Time: 22-04-2007 15:36:46	CRF Status: Entry Complete
Discrepancies: Closed	Modification Time: 18-09-2007 09:07:10	
Approval Status: Not Approved	Approval Time:	Approver:
Verification: Not Verified	Verification Time:	Verifier:
Comment:		

Section: Inc_Criteria	1 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 31-01-2007	
Entered By: Sherepta Mcleod		Entry Time: 22-04-2007 15:36:46	
		Last Modification Time: 17-09-2007 14:08:58	
		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: 31-01-2007	
Entered By: Sherepta Mcleod		Entry Time: 22-04-2007 15:36:46	
		Last Modification Time: 22-04-2007 15:45:05	
		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: 1002  
CRF: Screening  
Visit: SCREENING

Site: CB\_001  
Blank? N  
Visit Date: 31-01-2007

Investigator: C2474\_138  
CRF Page #: 2  
Document #: R138624813

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).	NOT AP
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: 31-01-2007	
Entered By: Sherepta Mcleod		Entry Time: 22-04-2007 15:36:46	
		Last Modification Time: 22-04-2007 15:45:05	
		Page number: 3	
Exclusion Criteria			
Sequence number			Yes/No
01	For Groups A, B, and C, regular use of any other tobacco or nicotine-containing product or device other than tobacco burning cigarettes from 6 months prior to the study through Week 24, including cigars, pipes, chewing tobacco, snuff, snus, nicotine patch, nicotine gum, etc.		NO
02	History or clinical manifestations of significant metabolic, hepatic, renal, hematological, pulmonary, cardiovascular, gastrointestinal, urological, neurological, or psychiatric disorders.		NO
03	History of hypersensitivity or allergies to any drug compound unless approved by the Investigator(s).		NO
04	History or presence of an abnormal ECG, which, in the Investsigator(s)' opinion, is clinically significant.		NO
05	History of alcoholism of 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: 1002

CRF: Screening

Visit: SCREENING

Site: CB\_001

Blank? N

Visit Date: 31-01-2007

Investigator: C2474\_138

CRF Page #: 2

Document #: R138624813

Section: Informed Consent	4 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 31-01-2007	
Entered By: Sherepta Mcleod		Entry Time: 22-04-2007 15:36:46	
		Last Modification Time: 22-04-2007 15:45:05	
		Page number: 4	
Informed Consent			
Date the Subject Signed the Smoker Informed Consent Form		31-01-2007	

Section: Elig		5 of 10	Blank? N		Section Status: Entry Complete	
Visit: SCREENING			Section Date: 31-01-2007			
Entered By: Sherepta Mcleod			Entry Time: 22-04-2007 15:36:46			
			Last Modification Time: 22-04-2007 15:45:05			
			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: 31-01-2007	
Entered By: Sherepta Mcleod		Entry Time: 22-04-2007 15:36:46	
		Last Modification Time: 22-04-2007 15:45:05	
		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: 31-01-2007			
Entered By: Sherepta Mcleod				Entry Time: 22-04-2007 15:36:46			
				Last Modification Time: 17-09-2007 14:27:23			
				Page number: 5			

Demographics		Subject Initials			
Date of Birth	Gender	Height	Height Unit	Weight	Weight Unit
(b) (6)	M	ND	NA	136	LB
		xxx.x		xxx.x	
Ethnicity					

# CRF Report for Study E6270229

Patient: 1002  
CRF: Screening  
Visit: SCREENING

Site: CB\_001  
Blank? N  
Visit Date: 31-01-2007

Investigator: C2474\_138  
CRF Page #: 2  
Document #: R138624813

Section: Demog 7 of 10

Hispanic or Latino? NO  
Race WHITE  
Race other

Section: Vital 8 of 10

Blank? N

Section Status: Entry Complete

Visit: SCREENING

Section Date: 31-01-2007

Entered By: Sherepta Mcleod

Entry Time: 22-04-2007 15:36:46

Last Modification Time: 22-04-2007 15:45:05

Page number: 5

## VITAL SIGNS

Actual Time	Blood Pressure		Pulse	Respiratory Rate	Oral Temperature	Unit
1327	Systolic 132	Diastolic 82	80	14	98.1	F
					xxx.x	

Comments

Section: Hdvf\_Oral\_Health 9 of 10

Blank? N

Section Status: Entry Complete

Visit: SCREENING

Section Date: 31-01-2007

Entered By: Sherepta Mcleod

Entry Time: 22-04-2007 15:36:46

Last Modification Time: 17-09-2007 14:17:08

Page number: 5

## HDYF? / ORAL HEALTH QUESTIONS INQUIRY

Actual Time	HDYF Performed?	Oral Health Questions Performed?	Comments
NR	YES	YES	

Section: Lab\_Eval 10 of 10

Blank? N

Section Status: Entry Complete

Visit: SCREENING

Section Date: 31-01-2007

Entered By: Sherepta Mcleod

Entry Time: 22-04-2007 15:36:46

Last Modification Time: 22-04-2007 15:45:05

Page number: 6

## Laboratory Evaluations

Were the scheduled laboratory samples obtained? YES No, specify

Requisition Number 1 N526679

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
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# CRF Report for Study E6270229

Patient: 1002	Site: CB_001	Investigator: C2474_138
CRF: Screening2	Blank? N	CRF Page #: 3
Visit: SCREENING	Visit Date: 31-01-2007	Document #: R138624913
Entered By: Sherepta Mcleod	Entry Time: 22-04-2007 15:45:06	CRF Status: Entry Complete
Discrepancies: Closed	Modification Time: 06-12-2007 18:07:18	
Approval Status: Not Approved	Approval Time:	Approver:
Verification: Not Verified	Verification Time:	Verifier:
Comment:		

Section: Preg_Test	1 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 31-01-2007	
Entered By: Sherepta Mcleod		Entry Time: 22-04-2007 15:45:06	
		Last Modification Time: 22-04-2007 15:54:03	
		Page number: 6	
Urine Pregnancy Test			
Result			
N/A,			
MALE			
OR			
FEMA			
LE			

Section: Urine_Drug	2 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 31-01-2007	
Entered By: Sherepta Mcleod		Entry Time: 22-04-2007 15:45:06	
		Last Modification Time: 22-04-2007 15:54:03	
		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: 31-01-2007	
Entered By: Sherepta Mcleod		Entry Time: 22-04-2007 15:45:06	
		Last Modification Time: 22-04-2007 15:54:03	
		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: 31-01-2007	

# CRF Report for Study E6270229

Patient: 1002  
CRF: Screening2  
Visit: SCREENING

Site: CB\_001  
Blank? N  
Visit Date: 31-01-2007

Investigator: C2474\_138  
CRF Page #: 3  
Document #: R138624913

Section: Med\_Hx 4 of 10

Entered By: Sherepta Mcleod

Entry Time: 22-04-2007 15:45:06  
Last Modification Time: 22-04-2007 15:54:03  
Page number: 7

## Medical History

Does the subject have any relevant medical history? NO

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

System	Diagnosis/Procedure	Date of Onset	Date of Resolution/Ongoing
--------	---------------------	---------------	----------------------------

Section: ECG 5 of 10

Blank? N

Section Status: Entry Complete

Visit: SCREENING

Section Date: 31-01-2007

Entered By: Sherepta Mcleod

Entry Time: 22-04-2007 15:45:06

Last Modification Time: 22-04-2007 15:54:03

Page number: 8

## 12-LEAD ELECTROCARDIOGRAM REPORT

Actual Time	Ventricular Heart Rate
1336	73

### Cardiac Cycle Measurements

PR Interval	QRS Duration	QT Interval	QTc Interval
140	106	376	398

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: 31-01-2007

Entered By: Sherepta Mcleod

Entry Time: 22-04-2007 15:45:06

Last Modification Time: 22-04-2007 15:54:03

Page number: 9

## USUAL BRAND CIGARETTE PACK

## DATA

Usual Brand	Type	Length
MACDONALD EXPORT A	NON-MENTHOL	KING SIZE 83-85MM
Style	Pack	How long have these been the subject's usual brand?
MILD/MEDIUMS	HARD	UNK months
		UNK years

Section: Ftc\_Tar\_Level 7 of 10

Blank? N

Section Status: Entry Complete

# CRF Report for Study E6270229

Patient: 1002  
CRF: Screening2  
Visit: SCREENING

Site: CB\_001  
Blank? N  
Visit Date: 31-01-2007

Investigator: C2474\_138  
CRF Page #: 3  
Document #: R138624913

Section: Ftc_Tar_Level	7 of 10	Section Date: 31-01-2007
Visit: SCREENING		Entry Time: 22-04-2007 15:45:06
Entered By: Sherepta Mcleod		Last Modification Time: 06-12-2007 18:07:18
		Page number: 9
FTC TAR LEVEL OF USUAL BRAND		
FTC Tar Level (mg)		
14.3		

Section: Expired_Carbon_M	8 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 31-01-2007	
Entered By: Sherepta Mcleod		Entry Time: 22-04-2007 15:45:06	
		Last Modification Time: 17-09-2007 14:18:22	
		Page number: 10	
EXPIRED CARBON MONOXIDE			
Actual Time	ECO Level (ppm)	%COHb	Comments
1252	28	NR	

Section: Best_Baseline_Sp	9 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 31-01-2007	
Entered By: Sherepta Mcleod		Entry Time: 22-04-2007 15:45:06	
		Last Modification Time: 22-04-2007 15:54:03	
		Page number: 10	
BEST BASELINE SPIROMETRY TEST RESULT			
Actual Time	Testing Position	FEV1 L	FEV 1 Predicted (%)
of FEV1/FVC Test			FVC L
1307	STANDING	4.35	109
			5.57
			113
			Comments

Section: Irvs_Training	10 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 31-01-2007	
Entered By: Sherepta Mcleod		Entry Time: 22-04-2007 15:45:06	
		Last Modification Time: 22-04-2007 15:54:03	
		Page number: 10	
IVRS TRAINING			
Did Subject receive training on the Daily Call-In Diary (IVRS)?			
YES			

# CRF Report for Study E6270229

Patient: 1002	Site: CB_001	Investigator: C2474_138
CRF: Week-2	Blank? N	CRF Page #: 4
Visit: WEEK -2	Visit Date: 09-02-2007	Document #: R138625013
Entered By: Sherepta Mcleod	Entry Time: 22-04-2007 15:54:04	CRF Status: Entry Complete
Discrepancies: None	Modification Time: 22-04-2007 15:54:48	
Approval Status: Not Approved	Approval Time:	Approver:
Verification: Not Verified	Verification Time:	Verifier:
Comment:		

Section: Usual_Brand_Coll	Blank? N	Section Status: Entry Complete								
Visit: WEEK -2	Section Date: 09-02-2007									
Entered By: Sherepta Mcleod	Entry Time: 22-04-2007 15:54:04									
	Last Modification Time: 22-04-2007 15:54:48									
	Page number: 11									
<table><thead><tr><th>USUAL BRAND</th><th>CIGARETTE COLLECTION TRAINING</th></tr></thead><tbody><tr><td>1. Did subject receive foam block?</td><td>YES</td></tr><tr><td>2. Did subject receive training on usual brand collection?</td><td>YES</td></tr><tr><td>3. Was subject provided usual brand cigarettes for Week 0 cigarette butt collection?</td><td>YES</td></tr></tbody></table>			USUAL BRAND	CIGARETTE COLLECTION TRAINING	1. Did subject receive foam block?	YES	2. Did subject receive training on usual brand collection?	YES	3. Was subject provided usual brand cigarettes for Week 0 cigarette butt collection?	YES
USUAL BRAND	CIGARETTE COLLECTION TRAINING									
1. Did subject receive foam block?	YES									
2. Did subject receive training on usual brand collection?	YES									
3. Was subject provided usual brand cigarettes for Week 0 cigarette butt collection?	YES									

# CRF Report for Study E6270229

Patient: 1002	Site: CB_001	Investigator: C2474_138
CRF: Week 0 Baseline	Blank? N	CRF Page #: 5
Visit: WEEK 0 (BASELINE)	Visit Date: 13-02-2007	Document #: R138671713
Entered By: Sherepta Mcleod	Entry Time: 23-04-2007 10:56:14	CRF Status: Entry Complete
Discrepancies: Closed	Modification Time: 21-11-2007 10:36:14	
Approval Status: Not Approved	Approval Time:	Approver:
Verification: Not Verified	Verification Time:	Verifier:
Comment:		

Section: Pro_Questionnaire	1 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 13-02-2007	
Entered By: Sherepta Mcleod		Entry Time: 23-04-2007 10:56:14	
		Last Modification Time: 23-04-2007 11:19:37	
		Page number: 12A	
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
13-02-2007			YES

Section: Urine Drug	2 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 13-02-2007	
Entered By: Sherepta Mcleod		Entry Time: 23-04-2007 10:56:14	
		Last Modification Time: 23-04-2007 11:19:37	
		Page number: 12A	
Drug Screen			
Date		Drug Screen Result	
13-02-2007		NEG	

Section: Alcohol_Screen	3 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 13-02-2007	
Entered By: Sherepta Mcleod		Entry Time: 23-04-2007 10:56:14	
		Last Modification Time: 17-09-2007 14:19:16	
		Page number: 12A	
Alcohol Screen			
Date		Breathalyzer Result	
13-02-2007		ND	

Section: Preg_Test	4 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 13-02-2007	
Entered By: Sherepta Mcleod		Entry Time: 23-04-2007 10:56:14	
		Last Modification Time: 23-04-2007 11:19:37	
		Page number: 12A	



# CRF Report for Study E6270229

Patient: 1002  
CRF: Week 0 Baseline  
Visit: WEEK 0 (BASELINE)

Site: CB\_001  
Blank? N  
Visit Date: 13-02-2007

Investigator: C2474\_138  
CRF Page #: 5  
Document #: R138671713

Section: Preg_Test		4 of 11	
Pregnancy Test			
Date	Result		
13-02-2007	N/A, MALE OR FEMA LE		

Section: Urine_Coll		5 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)		Section Date: 13-02-2007					
Entered By: Sherepta Mcleod		Entry Time: 23-04-2007 10:56:14					
		Last Modification Time: 17-09-2007 14:19:53					
		Page number: 12A					
24-Hour Urine Collection							
Scheduled Timepoint	Start Date	Start Time	Stop Date	Stop Time	Total Volume	Comments	
SPOT URINE VOID	13-02-2007	1455	NA	NA	NA		
0 HOUR TO 24 HOURS	13-02-2007	1455	14-02-2007	1509	1810		

Section: Hdyf_Oral_Health		6 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)		Section Date: 13-02-2007					
Entered By: Sherepta Mcleod		Entry Time: 23-04-2007 10:56:14					
		Last Modification Time: 17-09-2007 14:21:48					
		Page number: 13.1					
HDYF? INQUIRY							
Date	Actual Time	HDYF Performed?	Comments				
14-02-2007	0630	YES					

Section: Vital		7 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)		Section Date: 13-02-2007					
Entered By: Sherepta Mcleod		Entry Time: 23-04-2007 10:56:14					
		Last Modification Time: 17-09-2007 14:23:07					
		Page number: 13.1					
VITAL SIGNS							
		Blood Pressure				Oral	
Date	Actual Time	Systolic	Diastolic	Pulse	Respiratory Rate	Temperature	Unit
13-02-2007	1713	151	85	77	12	ND	ND

# CRF Report for Study E6270229

Patient: 1002  
CRF: Week 0 Baseline  
Visit: WEEK 0 (BASELINE)

Site: CB\_001  
Blank? N  
Visit Date: 13-02-2007

Investigator: C2474\_138  
CRF Page #: 5  
Document #: R138671713

Section: Vital	7 of 11	
		xxx.x
Comments		

Section: Oral_Health_Exam	8 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)	Section Date: 13-02-2007		
Entered By: Sherepta Mcleod	Entry Time: 23-04-2007 10:56:14		
	Last Modification Time: 17-09-2007 14:23:07		
	Page number: 13.1		
ORAL HEALTH EXAMINATION			
Date			
14-02-2007			
	Procedure	Relevant Findings?*	Findings
	ORAL HEALTH QUESTIONS PERFORMED	NO	
	EVIDENCE OF LEUKOPLAKIA	NO	
	OTHER ORAL KERATOSIS	NO	

Section: Phys_Exam	9 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)	Section Date: 13-02-2007		
Entered By: Sherepta Mcleod	Entry Time: 23-04-2007 10:56:14		
	Last Modification Time: 23-04-2007 11:19:37		
	Page number: 14.1		
PHYSICAL EXAMINATION			
Date			
14-02-2007			
	Code Number	Code	Relevant Findings?
	01	GENERAL	NO
	02	SKIN	NO
	03	HEENT	NO
	04	MOUTH	NO
	05	NECK	NO
	06	THORAX/LUNG	NO
	07	CARDIO	NO
	08	ABDOMEN	NO
	09	MUSCULO	NO
	10	NEURO	NO
	11	LYMPH	NO
	12	OTHER	NE

Section: Weight_Height	10 of 11	Blank? N	Section Status: Entry Complete
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# CRF Report for Study E6270229

Patient: 1002

Site: CB\_001

Investigator: C2474\_138

CRF: Week 0 Baseline

Blank? N

CRF Page #: 5

Visit: WEEK 0 (BASELINE)

Visit Date: 13-02-2007

Document #: R138671713

Section: Weight_Height	10 of 11	Section Date: 13-02-2007
Visit: WEEK 0 (BASELINE)		Entry Time: 23-04-2007 10:56:14
Entered By: Sherepta Mcleod		Last Modification Time: 23-04-2007 11:19:37
		Page number: 14.1

WEIGHT & HEIGHT				
Date	Weight	Unit	Height	Unit
13-02-2007	61.2	KG	170	CM
	xxx.x		xxx.x	

Section: Lab_Eval	11 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 13-02-2007	
Entered By: Sherepta Mcleod		Entry Time: 23-04-2007 10:56:14	
		Last Modification Time: 21-11-2007 10:36:14	
		Page number: 15.1	

Laboratory Evaluations				
Date				
14-02-2007				
Were the scheduled laboratory samples obtained?		YES	No, specify	
Requisition Number 1	N526699			
Requisition Number 2 (if applicable)	N527948			
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: 1002	Site: CB_001	Investigator: C2474_138
CRF: Week 0 2baseline	Blank? N	CRF Page #: 5.1
Visit: WEEK 0 (BASELINE)	Visit Date: 14-02-2007	Document #: R138675113
Entered By: Sherepta Mcleod	Entry Time: 23-04-2007 11:19:38	CRF Status: Entry Complete
Discrepancies: Closed	Modification Time: 26-11-2007 13:48:14	
Approval Status: Not Approved	Approval Time:	Approver:
Verification: Not Verified	Verification Time:	Verifier:
Comment:		

Section: Pk_Blood_Biomark	1 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 14-02-2007	
Entered By: Sherepta Mcleod		Entry Time: 23-04-2007 11:19:38	
		Last Modification Time: 23-04-2007 11:36:06	
		Page number: 15.1	
Blood Sampling For Biomarkers/Chemistry/Hematology (following an overnight fast)			
Date	Actual Time	Comments	
14-02-2007	0658		

Section: Expired Carbon M	2 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 14-02-2007	
Entered By: Sherepta Mcleod		Entry Time: 23-04-2007 11:19:38	
		Last Modification Time: 23-04-2007 11:36:06	
		Page number: 15.1	
EXPIRED CARBON MONOXIDE			
Date	Actual Time	ECO Level (ppm)	%COHb
14-02-2007	1319	34	6.0
Comments			

Section: Blood_Sampl_Cohb	3 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 14-02-2007	
Entered By: Sherepta Mcleod		Entry Time: 23-04-2007 11:19:38	
		Last Modification Time: 23-04-2007 11:36:06	
		Page number: 15.1	
Blood Sampling for %COHb			
Date	Actual Time	Comments	
14-02-2007	1324		

Section: Pre_Bronch_Spir	4 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 14-02-2007	
Entered By: Sherepta Mcleod		Entry Time: 23-04-2007 11:19:38	
		Last Modification Time: 26-11-2007 13:45:31	
		Page number: 16.1	

# CRF Report for Study E6270229

Patient: 1002

CRF: Week 0 2baseline

Visit: WEEK 0 (BASELINE)

Site: CB\_001

Blank? N

Visit Date: 14-02-2007

Investigator: C2474\_138

CRF Page #: 5.1

Document #: R138675113

Section: Pre_Bronch_Spir		4 of 11					
PRE-BRONCHODILATOR BEST BASELINE SPIROMETRY TEST RESULT							
Actual Time							
of FEV1/FVC		Testing				FVC	
Date	Test	Position	FEV1 L	FEV1 Predicted (%)	FVC L	Predicted (%)	Comments
14-02-2007	1358	STANDI NG	4.24	106	5.36	109	

Section: Proventil_Admin		5 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)		Section Date: 14-02-2007					
Entered By: Sherepta Mcleod		Entry Time: 23-04-2007 11:19:38					
		Last Modification Time: 23-04-2007 11:36:06					
		Page number: 16.1					
PROVENTIL ADMINISTRATION							
Actual Time							
of Proventil							
Date	Administration	Amount Administered	Comments				
14-02-2007	1404	2 METERED PUFFS					

Section: Post_Bronch_Spir		6 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)		Section Date: 14-02-2007					
Entered By: Sherepta Mcleod		Entry Time: 23-04-2007 11:19:38					
		Last Modification Time: 26-11-2007 13:48:14					
		Page number: 16.1					
POST-BRONCHODILATOR BEST SPIROMETRY TEST RESULT							
Actual Time							
of FEV1/FVC		Testing					
Date	Test	Position	FEV1 L	FEV1 Predicted (%)	FVC L	FVC Predicted (%)	Comments
14-02-2007	1427	STANDING	4.15	104	5.23	107	

Section: Unused_Usual_Bra		7 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)		Section Date: 14-02-2007					
Entered By: Sherepta Mcleod		Entry Time: 23-04-2007 11:19:38					
		Last Modification Time: 23-04-2007 11:36:06					
		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	
14-02-2007							

# CRF Report for Study E6270229

Patient: 1002

CRF: Week 0 2baseline

Visit: WEEK 0 (BASELINE)

Site: CB\_001

Blank? N

Visit Date: 14-02-2007

Investigator: C2474\_138

CRF Page #: 5.1

Document #: R138675113

Section: Usual_Brand_Butt		8 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)		Section Date: 14-02-2007		Entry Time: 23-04-2007 11:19:38			
Entered By: Sherepta Mcleod		Last Modification Time: 21-11-2007 11:04:34		Page number: 17.1			

Usual Brand Cigarette Butt Collection					Number of Usual Brand Cigarette Butts Collected	Any Product Deviation?	If yes, number of butts other than usual brand:	Comments
Scheduled Collection Period	Start Date	Start Time	Stop Date	Stop Time				
24 HOURS PRIOR TO CHECK-IN	12-02- 2004	NR	13-02-2007	NR	20	NO		
24 HOURS IN-HOUSE	13-02- 2007	NR	14-02-2007	1503	23	NO		

Section: Used_Butt_Measur		9 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)		Section Date: 14-02-2007		Entry Time: 23-04-2007 11:19:38			
Entered By: Sherepta Mcleod		Last Modification Time: 23-04-2007 11:36:06		Page number: 18.1			

USUAL BRAND CIGARETTE BUTT MEASUREMENT		
Date	Scheduled Collection Period	
12-02-2007	24 HOURS PRIOR TO CHECK-IN	

Cigarette Butt Number	Cigarette Butt Measurement (mm)
1	25
2	29
3	30
4	32
5	25
6	33
7	30
8	32
9	31
10	25
11	28
12	28
13	30
14	30
15	27
16	29
17	28

# CRF Report for Study E6270229

Patient: 1002

CRF: Week 0 2baseline

Visit: WEEK 0 (BASELINE)

Site: CB\_001

Blank? N

Visit Date: 14-02-2007

Investigator: C2474\_138

CRF Page #: 5.1

Document #: R138675113

Section: Used\_Butt\_Measur 9 of 11

18	29
19	30
20	32

Section: Used\_Butt\_Measur 10 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 14-02-2007

Entered By: Sherepta Mcleod

Entry Time: 23-04-2007 11:19:38

Last Modification Time: 23-04-2007 11:36:06

Page number: 19.1

## USUAL BRAND CIGARETTE BUTT MEASUREMENT

Scheduled Collection

Date  
13-02-2007

Period  
24 HOURS IN-HOUSE

Cigarette Butt Number

Cigarette Butt Measurement (mm)

1	25
2	27
3	25
4	25
5	23
6	23
7	23
8	24
9	27
10	32
11	27
12	25
13	26
14	23
15	19
16	25
17	23
18	24
19	24
20	23
21	27
22	23
23	19

Section: Randomization 11 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 14-02-2007

# CRF Report for Study E6270229

Patient: 1002

Site: CB\_001

Investigator: C2474\_138

CRF: Week 0 2baseline

Blank? N

CRF Page #: 5.1

Visit: WEEK 0 (BASELINE)

Visit Date: 14-02-2007

Document #: R138675113

Section: Randomization 11 of 11

Entered By: Sherepta Mcleod

Entry Time: 23-04-2007 11:19:38

Last Modification Time: 23-04-2007 11:36:06

Page number: 20.1

## RANDOMIZATION

Date	Actual Time	Randomization Sequence
14-02-2007	1451	GROUP B



# CRF Report for Study E6270229

Patient: 1002	Site: CB_001	Investigator: C2474_138
CRF: Week 0 3baseline	Blank? N	CRF Page #: 5.2
Visit: WEEK 0 (BASELINE)	Visit Date: 14-02-2007	Document #: R138677413
Entered By: Sherepta Mcleod	Entry Time: 23-04-2007 11:36:07	CRF Status: Entry Complete
Discrepancies: None	Modification Time: 18-09-2007 09:07:10	
Approval Status: Not Approved	Approval Time:	Approver:
Verification: Not Verified	Verification Time:	Verifier:
Comment:		

Section: Study_Prod_Dispe	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)	Section Date: 14-02-2007	
Entered By: Sherepta Mcleod	Entry Time: 23-04-2007 11:36:07	
	Last Modification Time: 13-09-2007 10:19:54	
	Page number: 23.1	

## STUDY PRODUCT DISPENSATION

Date	Actual Time	Product Dispensed	Flavor	Amount Dispensed
14-02-2007	1503	SNUS	ORIGINAL	1
14-02-2007	1503	SNUS	SPICE	1
14-02-2007	1503	SNUS	FROST	1

# CRF Report for Study E6270229

Patient: 1002

CRF: Intercurrent\_III

Visit: INTERCURRENT ILL

Entered By: Sherepta Mcleod

Discrepancies: Closed

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CB\_001

Blank? N

Visit Date: 14-02-2007

Entry Time: 25-04-2007 14:53:07

Modification Time: 21-11-2007 11:06:48

Approval Time:

Verification Time:

Investigator: C2474\_138

CRF Page #: 7

Document #: R139439613

CRF Status: Entry Complete

Approver:

Verifier:

Section: Ip_Findings		Blank? N		Section Status: Entry Complete				
Visit: INTERCURRENT ILL		Section Date: 14-02-2007						
Entered By: Sherepta Mcleod		Entry Time: 25-04-2007 14:53:07						
		Last Modification Time: 21-11-2007 11:06:48						
		Page number: 21						
Intercurrent Illness/Physical Findings								
Did the subject experience any intercurrent illness/findings from Screening to the first use of study product?								
YES								
Event No	Illness/Finding	Date	Onset Time	Date	Resolved / Changed Time	Severity	Relationship to Procedure	Action Taken
1	MALAISE	04-02-2007	1230	06-02-2007	UNK	MILD	NOT RELATED	NONE

# CRF Report for Study E6270229

Patient: 1002	Site: CB_001	Investigator: C2474_138
CRF: Week 1	Blank? N	CRF Page #: 8
Visit: WEEK 1	Visit Date: 21-02-2007	Document #: R139450213
Entered By: Sherepta Mcleod	Entry Time: 25-04-2007 15:08:55	CRF Status: Entry Complete
Discrepancies: Active	Modification Time: 26-11-2007 10:16:26	
Approval Status: Not Approved	Approval Time:	Approver:
Verification: Not Verified	Verification Time:	Verifier:
Comment:		

Section: Hdyf_Oral_Health	1 of 5	Blank? N	Section Status: Entry Complete
Visit: WEEK 1	Section Date: 21-02-2007		
Entered By: Sherepta Mcleod	Entry Time: 25-04-2007 15:08:55		
	Last Modification Time: 17-09-2007 15:00:46		
	Page number: 22		
HDYF? / ORAL HEALTH QUESTIONS INQUIRY			
		Oral Health Questions Performed?	Comments
Actual Time	HDYF Performed?		
NR	YES	YES	

Section: Vital	2 of 5	Blank? N	Section Status: Entry Complete		
Visit: WEEK 1	Section Date: 21-02-2007				
Entered By: Sherepta Mcleod	Entry Time: 25-04-2007 15:08:55				
	Last Modification Time: 25-04-2007 15:14:39				
	Page number: 22				
VITAL SIGNS					
Actual Time	Blood Pressure	Pulse	Respiratory Rate	Oral Temperature	Unit
1225	Systolic 136	Diastolic 86	64	12	36.4 C
				xxx.x	
Comments					

Section: Expired_Carbon_M	3 of 5	Blank? N	Section Status: Entry Complete
Visit: WEEK 1	Section Date: 21-02-2007		
Entered By: Sherepta Mcleod	Entry Time: 25-04-2007 15:08:55		
	Last Modification Time: 17-09-2007 14:59:24		
	Page number: 22		
EXPIRED CARBON MONOXIDE			
Actual Time	ECO Level (ppm)	%COHb	Comments
1222	23	4.3	

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

Patient: 1002

CRF: Week 1

Visit: WEEK 1

Site: CB\_001

Blank? N

Visit Date: 21-02-2007

Investigator: C2474\_138

CRF Page #: 8

Document #: R139450213

Section: Unused\_Study\_Pro 4 of 5

Visit: WEEK 1

Entered By: Sherepta Mcleod

Section Date: 21-02-2007

Entry Time: 25-04-2007 15:08:55

Last Modification Time: 21-11-2007 12:28:47

Page number: 23

## Unused Study Product Returned

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

Section: Study\_Prod\_Dispe 5 of 5

Visit: WEEK 1

Entered By: Sherepta Mcleod

Blank? N

Section Date: 21-02-2007

Entry Time: 25-04-2007 15:08:55

Last Modification Time: 17-09-2007 14:44:02

Page number: 23

Section Status: Entry Complete

## STUDY PRODUCT DISPENSATION

Actual Time	Product Dispensed	Flavor	Amount Dispensed
NR	SNUS	ORIGINAL	1
NR	SNUS	FROST	1

# CRF Report for Study E6270229

Patient: 1002	Site: CB_001	Investigator: C2474_138
CRF: Week 2	Blank? N	CRF Page #: 9
Visit: WEEK 2	Visit Date: 28-02-2007	Document #: R139481913
Entered By: Sherepta Mcleod	Entry Time: 25-04-2007 16:05:56	CRF Status: Entry Complete
Discrepancies: Active	Modification Time: 26-11-2007 10:16:26	
Approval Status: Not Approved	Approval Time:	Approver:
Verification: Not Verified	Verification Time:	Verifier:
Comment:		

Section: Hdyf_Oral_Health	1 of 6	Blank? N	Section Status: Entry Complete	
Visit: WEEK 2		Section Date: 28-02-2007		
Entered By: Sherepta Mcleod		Entry Time: 25-04-2007 16:05:56		
		Last Modification Time: 17-09-2007 15:00:31		
		Page number: 24		
HDYF? / ORAL HEALTH QUESTIONS INQUIRY				
		Oral Health Questions		
Actual Time	HDYF Performed?	Performed?	Comments	
NR	YES	YES		

Section: Vital	2 of 6	Blank? N	Section Status: Entry Complete			
Visit: WEEK 2		Section Date: 28-02-2007				
Entered By: Sherepta Mcleod		Entry Time: 25-04-2007 16:05:56				
		Last Modification Time: 25-04-2007 16:08:11				
		Page number: 24				
VITAL SIGNS						
Actual Time	Blood Pressure		Pulse	Respiratory Rate	Oral Temperature	Unit
1213	Systolic 120	Diastolic 070	72	12	36.8	C
					xxx.x	
Comments						

Section: Expired_Carbon_M	3 of 6	Blank? N	Section Status: Entry Complete		
Visit: WEEK 2		Section Date: 28-02-2007			
Entered By: Sherepta Mcleod		Entry Time: 25-04-2007 16:05:56			
		Last Modification Time: 25-04-2007 16:08:11			
		Page number: 24			
EXPIRED CARBON MONOXIDE					
Actual Time	ECO Level (ppm)		%COHb	Comments	
1219	25		4.6		

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

Patient: 1002

CRF: Week 2

Visit: WEEK 2

Site: CB\_001

Blank? N

Visit Date: 28-02-2007

Investigator: C2474\_138

CRF Page #: 9

Document #: R139481913

Section: Blood\_Sampl\_Cohb 4 of 6

Visit: WEEK 2

Entered By: Sherepta Mcleod

Section Date: 28-02-2007

Entry Time: 25-04-2007 16:05:56

Last Modification Time: 25-04-2007 16:08:11

Page number: 24

Blood Sampling for %COHb

Actual Time Comments

1225

Section: Unused\_Study\_Pro 5 of 6

Blank? N

Section Status: Entry Complete

Visit: WEEK 2

Section Date: 28-02-2007

Entry Time: 25-04-2007 16:05:56

Last Modification Time: 21-11-2007 12:37:31

Page number: 25

Unused Study Product Returned

Amount Returned

Product Returned

Flavor

Packs

Individual Cigarettes / pouches

SNUS

ORIGINAL

0

NR

SNUS

FROST

0

NR

Section: Study\_Prod\_Dispe 6 of 6

Blank? N

Section Status: Entry Complete

Visit: WEEK 2

Section Date: 28-02-2007

Entry Time: 25-04-2007 16:05:56

Last Modification Time: 17-09-2007 15:03:57

Page number: 25

STUDY PRODUCT DISPENSATION

Actual Time

Product Dispensed

Flavor

Amount Dispensed

NR

SNUS

ORIGINAL

2

# CRF Report for Study E6270229

Patient: 1002	Site: CB_001	Investigator: C2474_138
CRF: Week 4	Blank? Y	CRF Page #: 10
Visit: WEEK 4	Visit Date: 13-03-2007	Document #: R156915713
Entered By: Sherepta Mcleod	Entry Time: 17-09-2007 15:05:46	CRF Status: Created
Discrepancies: None	Modification Time:	Approver:
Approval Status: Not Approved	Approval Time:	Verifier:
Verification: Not Verified	Verification Time:	
Comment:		

Section: Pro_Questionnair	1 of 6	Blank? Y	Section Status: Created
Visit: WEEK 4		Section Date: 13-03-2007	
Entered By: Sherepta Mcleod		Entry Time: 17-09-2007 15:05:46	
		Last Modification Time:	
		Page number: 26	
PRO QUESTIONNAIRES			
With the possible exception of urinating, did subject complete Smoker Core Questionnaire PRIOR to any study procedures being performed?			YES / NO

Section: Hdyf Oral Health	2 of 6	Blank? Y	Section Status: Created
Visit: WEEK 4		Section Date: 13-03-2007	
Entered By: Sherepta Mcleod		Entry Time: 17-09-2007 15:05:46	
		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: 13-03-2007	
Entered By: Sherepta Mcleod		Entry Time: 17-09-2007 15:05:46	
		Last Modification Time:	
		Page number: 26	
VITAL SIGNS			
Actual Time	Blood Pressure	Pulse	Respiratory Rate
	Systolic	Diastolic	Temperature
			xxx.x
Unit			
Comments			

Section: Expired_Carbon_M	4 of 6	Blank? Y	Section Status: Created
Visit: WEEK 4		Section Date: 13-03-2007	

# CRF Report for Study E6270229

Patient: 1002

CRF: Week 4

Visit: WEEK 4

Site: CB\_001

Blank? Y

Visit Date: 13-03-2007

Investigator: C2474\_138

CRF Page #: 10

Document #: R156915713

Section: Expired\_Carbon\_M 4 of 6

Entered By: Sherepta Mcleod

Entry Time: 17-09-2007 15:05:46

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: 13-03-2007

Entered By: Sherepta Mcleod

Entry Time: 17-09-2007 15:05:46

Last Modification Time:

Page number: 27

## Unused Study Product Returned

Product Returned	Flavor	Amount Returned	
		Packs	Individual Cigarettes / pouches

Section: Study\_Prod\_Dispe 6 of 6

Blank? Y

Section Status: Created

Visit: WEEK 4

Section Date: 13-03-2007

Entered By: Sherepta Mcleod

Entry Time: 17-09-2007 15:05:46

Last Modification Time:

Page number: 27

## STUDY PRODUCT DISPENSATION

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

Patient: 1002

CRF: Week 6

Visit: WEEK 6

Entered By: Sherepta Mcleod

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CB\_001

Blank? Y

Visit Date: 13-03-2007

Entry Time: 17-09-2007 15:06:05

Modification Time:

Approval Time:

Verification Time:

Investigator: C2474\_138

CRF Page #: 11

Document #: R156915913

CRF Status: Created

Approver:

Verifier:

Section: Hdvf_Oral_Health	1 of 5	Blank? Y	Section Status: Created
Visit: WEEK 6		Section Date: 13-03-2007	
Entered By: Sherepta Mcleod		Entry Time: 17-09-2007 15:06:05	
		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: 13-03-2007	
Entered By: Sherepta Mcleod		Entry Time: 17-09-2007 15:06:05	
		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: 13-03-2007	
Entered By: Sherepta Mcleod		Entry Time: 17-09-2007 15:06:05	
		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: 13-03-2007	
Entered By: Sherepta Mcleod		Entry Time: 17-09-2007 15:06:05	
		Last Modification Time:	

# CRF Report for Study E6270229

Patient: 1002  
CRF: Week 6  
Visit: WEEK 6

Site: CB\_001  
Blank? Y  
Visit Date: 13-03-2007

Investigator: C2474\_138  
CRF Page #: 11  
Document #: R156915913

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: 13-03-2007	
Entered By: Sherepta Mcleod		Entry Time: 17-09-2007 15:06:05	
		Last Modification Time:	
		Page number: 29	
STUDY PRODUCT DISPENSATION			
Actual Time	Product Dispensed	Flavor	Amount Dispensed

# CRF Report for Study E6270229

Patient: 1002

CRF: Week 8

Visit: WEEK 8

Entered By: Sherepta Mcleod

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CB\_001

Blank? Y

Visit Date: 13-03-2007

Entry Time: 17-09-2007 15:06:15

Modification Time:

Approval Time:

Verification Time:

Investigator: C2474\_138

CRF Page #: 13

Document #: R156916013

CRF Status: Created

Approver:

Verifier:

Section: Pro_Questionnair	1 of 6	Blank? Y	Section Status: Created
Visit: WEEK 8		Section Date: 13-03-2007	
Entered By: Sherepta Mcleod		Entry Time: 17-09-2007 15:06:15	
		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: 13-03-2007	
Entered By: Sherepta Mcleod		Entry Time: 17-09-2007 15:06:15	
		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: 13-03-2007	
Entered By: Sherepta Mcleod		Entry Time: 17-09-2007 15:06:15	
		Last Modification Time:	
		Page number: 30	
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 8		Section Date: 13-03-2007	

# CRF Report for Study E6270229

Patient: 1002

CRF: Week 8

Visit: WEEK 8

Site: CB\_001

Blank? Y

Visit Date: 13-03-2007

Investigator: C2474\_138

CRF Page #: 13

Document #: R156916013

Section: Expired\_Carbon\_M 4 of 6

Entered By: Sherepta Mcleod

Entry Time: 17-09-2007 15:06:15

Last Modification Time:

Page number: 30

## EXPIRED CARBON MONOXIDE

Actual Time	ECO Level (ppm)	%COHb	Comments
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Section: Unused\_Study\_Pro 5 of 6

Blank? Y

Section Status: Created

Visit: WEEK 8

Section Date: 13-03-2007

Entered By: Sherepta Mcleod

Entry Time: 17-09-2007 15:06:15

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: 13-03-2007

Entered By: Sherepta Mcleod

Entry Time: 17-09-2007 15:06:15

Last Modification Time:

Page number: 31

## STUDY PRODUCT DISPENSATION

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

Patient: 1002

CRF: Week 10

Visit: WEEK 10

Site: CB\_001

Blank? Y

Visit Date: 13-03-2007

Investigator: C2474\_138

CRF Page #: 14

Document #: R156916113

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: 13-03-2007

Entered By: Sherepta Mcleod

Entry Time: 17-09-2007 15:06:27

Last Modification Time:

Page number: 33

## STUDY PRODUCT DISPENSATION

Actual Time

Product Dispensed

Flavor

Amount Dispensed

# CRF Report for Study E6270229

Patient: 1002	Site: CB_001	Investigator: C2474_138
CRF: Week 12	Blank? Y	CRF Page #: 15
Visit: WEEK 12	Visit Date: 13-03-2007	Document #: R156916213
Entered By: Sherepta Mcleod	Entry Time: 17-09-2007 15:06:37	CRF Status: Created
Discrepancies: None	Modification Time:	Approver:
Approval Status: Not Approved	Approval Time:	Verifier:
Verification: Not Verified	Verification Time:	
Comment:		

Section: Pro_Questionnaire	1 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12	Section Date: 13-03-2007		
Entered By: Sherepta Mcleod	Entry Time: 17-09-2007 15:06:37		
	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: 13-03-2007		
Entered By: Sherepta Mcleod	Entry Time: 17-09-2007 15:06:37		
	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: 13-03-2007		
Entered By: Sherepta Mcleod	Entry Time: 17-09-2007 15:06:37		
	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: 13-03-2007		
Entered By: Sherepta Mcleod	Entry Time: 17-09-2007 15:06:37		
	Last Modification Time:		
	Page number: 34		
Pregnancy Test			

# CRF Report for Study E6270229

Patient: 1002  
CRF: Week 12  
Visit: WEEK 12

Site: CB\_001  
Blank? Y  
Visit Date: 13-03-2007

Investigator: C2474\_138  
CRF Page #: 15  
Document #: R156916213

Section: Preg_Test	4 of 11
Date	Result

Section: Urine_Coll	5 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 13-03-2007	
Entered By: Sherepta Mcleod		Entry Time: 17-09-2007 15:06:37	
		Last Modification Time:	
		Page number: 34	
24-Hour Urine Collection			
Scheduled Timepoint	Start Date	Start Time	Stop Date
		Stop Time	Total Volume
Comments			

Section: Hdyf_Oral_Health	6 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 13-03-2007	
Entered By: Sherepta Mcleod		Entry Time: 17-09-2007 15:06:37	
		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: 13-03-2007	
Entered By: Sherepta Mcleod		Entry Time: 17-09-2007 15:06:37	
		Last Modification Time:	
		Page number: 35	
VITAL SIGNS			
		Blood Pressure	Oral
Date	Actual Time	Systolic	Diastolic
		Pulse	Respiratory Rate
		Temperature	Unit
xxx.x			
Comments			

Section: Oral_Health_Exam	8 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 13-03-2007	
Entered By: Sherepta Mcleod		Entry Time: 17-09-2007 15:06:37	
		Last Modification Time:	
		Page number: 35	
ORAL HEALTH EXAMINATION			



# CRF Report for Study E6270229

Patient: 1002  
CRF: Week 12  
Visit: WEEK 12

Site: CB\_001  
Blank? Y  
Visit Date: 13-03-2007

Investigator: C2474\_138  
CRF Page #: 15  
Document #: R156916213

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: 13-03-2007	
Entered By: Sherepta Mcleod		Entry Time: 17-09-2007 15:06:37	
		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: 13-03-2007	
Entered By: Sherepta Mcleod		Entry Time: 17-09-2007 15:06:37	
		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: 13-03-2007	
Entered By: Sherepta Mcleod		Entry Time: 17-09-2007 15:06:37	
		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: 1002	Site: CB_001	Investigator: C2474_138
CRF: Week 12(2)	Blank? Y	CRF Page #: 16
Visit: WEEK 12	Visit Date: 00-00-	Document #: R156916313
Entered By: Sherepta Mcleod	Entry Time: 17-09-2007 15:06:49	CRF Status: Created
Discrepancies: None	Modification Time:	Approver:
Approval Status: Not Approved	Approval Time:	Verifier:
Verification: Not Verified	Verification Time:	
Comment:		

Section: Pk_Blood_Biomark	1 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12	Section Date: 00-00-		
Entered By: Sherepta Mcleod	Entry Time: 17-09-2007 15:06:49		
	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: 00-00-		
Entered By: Sherepta Mcleod	Entry Time: 17-09-2007 15:06:49		
	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: 00-00-		
Entered By: Sherepta Mcleod	Entry Time: 17-09-2007 15:06:49		
	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: 00-00-		
Entered By: Sherepta Mcleod	Entry Time: 17-09-2007 15:06:49		
	Last Modification Time:		
	Page number: 38		
PRE-BRONCHODILATOR BEST BASELINE SPIROMETRY TEST RESULT			
Actual Time			

# CRF Report for Study E6270229

Patient: 1002  
CRF: Week 12(2)  
Visit: WEEK 12

Site: CB\_001  
Blank? Y  
Visit Date: 00-00-

Investigator: C2474\_138  
CRF Page #: 16  
Document #: R156916313

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

Section: Proventil_Admin Visit: WEEK 12 Entered By: Sherepta Mcleod	5 of 11	Blank? Y	Section Date: 00-00- Entry Time: 17-09-2007 15:06:49 Last Modification Time: Page number: 38	Section Status: Created
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PROVENTIL ADMINISTRATION			
	Actual Time of Proventil		
Date	Administration	Amount Administered	Comments

Section: Post_Bronch_Spir Visit: WEEK 12 Entered By: Sherepta Mcleod	6 of 11	Blank? Y	Section Date: 00-00- Entry Time: 17-09-2007 15:06:49 Last Modification Time: Page number: 38	Section Status: Created
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POST-BRONCHODILATOR BEST SPIROMETRY TEST RESULT			
	Actual Time of FEV1/FVC		
Date	Test	Position	FEV1 L    FEV1 Predicted (%)    FVC L    FVC Predicted (%)    Comments

Section: Used Study Tobac Visit: WEEK 12 Entered By: Sherepta Mcleod	7 of 11	Blank? Y	Section Date: 00-00- Entry Time: 17-09-2007 15:06:49 Last Modification Time: Page number: 39	Section Status: Created
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USED STUDY TOBACCO-HEATING CIGARETTE COLLECTION							
		Number of Study Tobacco-Heating	Weight of Cigarettes Collected	Any Product Deviation?	If yes, # of other Brand		Comments
Scheduled Collection Timepoint	Start Date	Start Time	Stop Date	Stop Time	Cigarettes Collected	(g)	

Section: Used_Study_Snus Visit: WEEK 12 Entered By: Sherepta Mcleod	8 of 11	Blank? Y	Section Date: 00-00- Entry Time: 17-09-2007 15:06:49	Section Status: Created
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# CRF Report for Study E6270229

Patient: 1002  
CRF: Week 12(2)  
Visit: WEEK 12

Site: CB\_001  
Blank? Y  
Visit Date: 00-00-

Investigator: C2474\_138  
CRF Page #: 16  
Document #: R156916313

Section: Used\_Study\_Snus 8 of 11

Last Modification Time:

Page number: 40

## USED STUDY SNUS COLLECTION

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

Section: Used\_Study\_Burn 9 of 11

Blank? Y

Section Status: Created

Visit: WEEK 12

Section Date: 00-00-

Entered By: Sherepta Mcleod

Entry Time: 17-09-2007 15:06:49

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
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Section: Used\_Butt\_Measur 10 of 11

Blank? Y

Section Status: Created

Visit: WEEK 12

Section Date: 00-00-

Entered By: Sherepta Mcleod

Entry Time: 17-09-2007 15:06:49

Last Modification Time:

Page number: 42

## USUAL STUDY TOBACCO-BURNING CIGARETTE BUTT MEASUREMENT

Scheduled Collection Date	Period	Cigarette Butt Number	Cigarette Butt Measurement (mm)
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Section: Used\_Butt\_Measur 11 of 11

Blank? Y

Section Status: Created

Visit: WEEK 12

Section Date: 00-00-

Entered By: Sherepta Mcleod

Entry Time: 17-09-2007 15:06:49

Last Modification Time:

Page number: 43

## USUAL STUDY TOBACCO-BURNING CIGARETTE BUTT MEASUREMENT

Scheduled Collection Date	Period	Cigarette Butt Number	Cigarette Butt Measurement (mm)
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# CRF Report for Study E6270229

Patient: 1002	Site: CB_001	Investigator: C2474_138
CRF: Week 12(3)	Blank? Y	CRF Page #: 17
Visit: WEEK 12	Visit Date: 00-00-	Document #: R156916513
Entered By: Sherepta Mcleod	Entry Time: 17-09-2007 15:07:01	CRF Status: Created
Discrepancies: None	Modification Time:	
Approval Status: Not Approved	Approval Time:	Approver:
Verification: Not Verified	Verification Time:	Verifier:
Comment:		

Section: Unused_Study_Pro	1 of 2	Blank? Y	Section Status: Created	
Visit: WEEK 12		Section Date: 00-00-		
Entered By: Sherepta Mcleod		Entry Time: 17-09-2007 15:07:01		
		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: 00-00-		
Entered By: Sherepta Mcleod		Entry Time: 17-09-2007 15:07:01		
		Last Modification Time:		
		Page number: 44		
STUDY PRODUCT DISPENSATION				
Date	Actual Time	Product Dispensed	Flavor	Amount Dispensed

# CRF Report for Study E6270229

Patient: 1002	Site: CB_001	Investigator: C2474_138
CRF: Week 14	Blank? Y	CRF Page #: 18
Visit: WEEK 14	Visit Date: 13-03-2007	Document #: R156916613
Entered By: Sherepta Mcleod	Entry Time: 17-09-2007 15:07:07	CRF Status: Created
Discrepancies: None	Modification Time:	
Approval Status: Not Approved	Approval Time:	Approver:
Verification: Not Verified	Verification Time:	Verifier:
Comment:		

Section: Hdyf_Oral_Health	1 of 5	Blank? Y	Section Status: Created
Visit: WEEK 14	Section Date: 13-03-2007	Entry Time: 17-09-2007 15:07:07	
Entered By: Sherepta Mcleod	Last Modification Time:	Page number: 45	
<p align="center">HDYF? / ORAL HEALTH QUESTIONS INQUIRY</p> <p align="center">Oral Health Questions Performed?</p>			
Actual Time	HDYF Performed?	Comments	

Section: Expired Carbon M	2 of 5	Blank? Y	Section Status: Created
Visit: WEEK 14	Section Date: 13-03-2007	Entry Time: 17-09-2007 15:07:07	
Entered By: Sherepta Mcleod	Last Modification Time:	Page number: 45	
<p align="center">EXPIRED CARBON MONOXIDE</p>			
Actual Time	ECO Level (ppm)	%COHb	Comments

Section: Vital	3 of 5	Blank? Y	Section Status: Created
Visit: WEEK 14	Section Date: 13-03-2007	Entry Time: 17-09-2007 15:07:07	
Entered By: Sherepta Mcleod	Last Modification Time:	Page number: 45	
<p align="center">VITAL SIGNS</p>			
Actual Time	Blood Pressure	Oral Temperature	Unit
	Systolic Diastolic	Pulse Respiratory Rate	xxx.x
Comments			

Section: Unused_Study_Pro	4 of 5	Blank? Y	Section Status: Created
Visit: WEEK 14	Section Date: 13-03-2007	Entry Time: 17-09-2007 15:07:07	
Entered By: Sherepta Mcleod	Last Modification Time:		

# CRF Report for Study E6270229

Patient: 1002

CRF: Week 14

Visit: WEEK 14

Site: CB\_001

Blank? Y

Visit Date: 13-03-2007

Investigator: C2474\_138

CRF Page #: 18

Document #: R156916613

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: 13-03-2007

Entered By: Sherepta Mcleod

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

Last Modification Time:

Page number: 46

## STUDY PRODUCT DISPENSATION

Actual Time

Product Dispensed

Flavor

Amount Dispensed

# CRF Report for Study E6270229

Patient: 1002	Site: CB_001	Investigator: C2474_138
CRF: Week 16	Blank? Y	CRF Page #: 19
Visit: WEEK 16	Visit Date: 13-03-2007	Document #: R156916813
Entered By: Sherepta Mcleod	Entry Time: 17-09-2007 15:07:34	CRF Status: Created
Discrepancies: None	Modification Time:	Approver:
Approval Status: Not Approved	Approval Time:	Verifier:
Verification: Not Verified	Verification Time:	
Comment:		

Section: Pro_Questionnair	1 of 6	Blank? Y	Section Status: Created
Visit: WEEK 16		Section Date: 13-03-2007	
Entered By: Sherepta Mcleod		Entry Time: 17-09-2007 15:07:34	
		Last Modification Time:	
		Page number: 47	
<p align="center">PRO QUESTIONNAIRES</p> <p>With the possible exception of urinating, did subject complete Smoker Core Questionnaire PRIOR to any study procedures being performed?</p>			YES / NO

Section: Hdyl Oral Health	2 of 6	Blank? Y	Section Status: Created												
Visit: WEEK 16		Section Date: 13-03-2007													
Entered By: Sherepta Mcleod		Entry Time: 17-09-2007 15:07:34													
		Last Modification Time:													
		Page number: 47													
<p align="center">HDYF? / ORAL HEALTH QUESTIONS INQUIRY</p> <table border="0"> <tr> <td></td> <td></td> <td>Oral Health</td> <td></td> </tr> <tr> <td></td> <td></td> <td>Questions</td> <td></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: 13-03-2007																						
Entered By: Sherepta Mcleod		Entry Time: 17-09-2007 15:07:34																						
		Last Modification Time:																						
		Page number: 47																						
<p align="center">VITAL SIGNS</p> <table border="0"> <tr> <td></td> <td align="center" colspan="2">Blood Pressure</td> <td></td> <td></td> <td align="center">Oral</td> <td></td> </tr> <tr> <td>Actual Time</td> <td align="center">Systolic</td> <td align="center">Diastolic</td> <td align="center">Pulse</td> <td align="center">Respiratory Rate</td> <td align="center">Temperature xxx.x</td> <td align="center">Unit</td> </tr> <tr> <td colspan="7">Comments</td> </tr> </table>					Blood Pressure				Oral		Actual Time	Systolic	Diastolic	Pulse	Respiratory Rate	Temperature xxx.x	Unit	Comments						
	Blood Pressure				Oral																			
Actual Time	Systolic	Diastolic	Pulse	Respiratory Rate	Temperature xxx.x	Unit																		
Comments																								

Section: Expired_Carbon_M	4 of 6	Blank? Y	Section Status: Created
Visit: WEEK 16		Section Date: 13-03-2007	



# CRF Report for Study E6270229

Patient: 1002

CRF: Week 16

Visit: WEEK 16

Site: CB\_001

Blank? Y

Visit Date: 13-03-2007

Investigator: C2474\_138

CRF Page #: 19

Document #: R156916813

Section: Expired\_Carbon\_M 4 of 6

Entered By: Sherepta Mcleod

Entry Time: 17-09-2007 15:07:34

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: 13-03-2007

Entered By: Sherepta Mcleod

Entry Time: 17-09-2007 15:07:34

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: 13-03-2007

Entered By: Sherepta Mcleod

Entry Time: 17-09-2007 15:07:34

Last Modification Time:

Page number: 48

## STUDY PRODUCT DISPENSATION

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

# CRF Report for Study E6270229

Patient: 1002	Site: CB_001	Investigator: C2474_138
CRF: Week 18	Blank? Y	CRF Page #: 20
Visit: WEEK 18	Visit Date: 13-03-2007	Document #: R156917113
Entered By: Sherepta Mcleod	Entry Time: 17-09-2007 15:07:47	CRF Status: Created
Discrepancies: None	Modification Time:	
Approval Status: Not Approved	Approval Time:	Approver:
Verification: Not Verified	Verification Time:	Verifier:
Comment:		

Section: Hdyl_Oral_Health	1 of 5	Blank? Y	Section Status: Created
Visit: WEEK 18	Section Date: 13-03-2007		
Entered By: Sherepta Mcleod	Entry Time: 17-09-2007 15:07:47		
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: 13-03-2007		
Entered By: Sherepta Mcleod	Entry Time: 17-09-2007 15:07:47		
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: 13-03-2007		
Entered By: Sherepta Mcleod	Entry Time: 17-09-2007 15:07:47		
Last Modification Time:			
Page number: 49			
VITAL SIGNS			
Actual Time	Blood Pressure	Pulse	Respiratory Rate
	Systolic Diastolic		Temperature
			xxx.x
Unit			
Comments			

Section: Unused_Study_Pro	4 of 5	Blank? Y	Section Status: Created
Visit: WEEK 18	Section Date: 13-03-2007		
Entered By: Sherepta Mcleod	Entry Time: 17-09-2007 15:07:47		
Last Modification Time:			

# CRF Report for Study E6270229

Patient: 1002

CRF: Week 18

Visit: WEEK 18

Site: CB\_001

Blank? Y

Visit Date: 13-03-2007

Investigator: C2474\_138

CRF Page #: 20

Document #: R156917113

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: 13-03-2007

Entered By: Sherepta Mcleod

Entry Time: 17-09-2007 15:07:47

Last Modification Time:

Page number: 50

## STUDY PRODUCT DISPENSATION

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

# CRF Report for Study E6270229

Patient: 1002	Site: CB_001	Investigator: C2474_138
CRF: Week 20	Blank? Y	CRF Page #: 21
Visit: WEEK 20	Visit Date: 13-03-2007	Document #: R156917213
Entered By: Sherepta Mcleod	Entry Time: 17-09-2007 15:07:56	CRF Status: Created
Discrepancies: None	Modification Time:	
Approval Status: Not Approved	Approval Time:	Approver:
Verification: Not Verified	Verification Time:	Verifier:
Comment:		

Section: Pro_Questionnair	1 of 6	Blank? Y	Section Status: Created
Visit: WEEK 20		Section Date: 13-03-2007	
Entered By: Sherepta Mcleod		Entry Time: 17-09-2007 15:07:56	
		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: Hdyl Oral Health	2 of 6	Blank? Y	Section Status: Created
Visit: WEEK 20		Section Date: 13-03-2007	
Entered By: Sherepta Mcleod		Entry Time: 17-09-2007 15:07:56	
		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: 13-03-2007	
Entered By: Sherepta Mcleod		Entry Time: 17-09-2007 15:07:56	
		Last Modification Time:	
		Page number: 51	
VITAL SIGNS			
Actual Time	Blood Pressure	Pulse	Respiratory Rate
	Systolic	Diastolic	Temperature
			xxx.x
Unit			
Comments			

Section: Expired_Carbon_M	4 of 6	Blank? Y	Section Status: Created
Visit: WEEK 20		Section Date: 13-03-2007	

# CRF Report for Study E6270229

Patient: 1002

CRF: Week 20

Visit: WEEK 20

Site: CB\_001

Blank? Y

Visit Date: 13-03-2007

Investigator: C2474\_138

CRF Page #: 21

Document #: R156917213

Section: Expired\_Carbon\_M 4 of 6

Entered By: Sherepta Mcleod

Entry Time: 17-09-2007 15:07:56

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: 13-03-2007

Entered By: Sherepta Mcleod

Entry Time: 17-09-2007 15:07:56

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: 13-03-2007

Entered By: Sherepta Mcleod

Entry Time: 17-09-2007 15:07:56

Last Modification Time:

Page number: 52

## STUDY PRODUCT DISPENSATION

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

# CRF Report for Study E6270229

Patient: 1002

CRF: Week 22

Visit: WEEK 22

Entered By: Sherepta Mcleod

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CB\_001

Blank? Y

Visit Date: 13-03-2007

Entry Time: 17-09-2007 15:08:05

Modification Time:

Approval Time:

Verification Time:

Investigator: C2474\_138

CRF Page #: 22

Document #: R156917313

CRF Status: Created

Approver:

Verifier:

Section: Hdyf_Oral_Health	1 of 5	Blank? Y	Section Status: Created
Visit: WEEK 22		Section Date: 13-03-2007	
Entered By: Sherepta Mcleod		Entry Time: 17-09-2007 15:08:05	
		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: 13-03-2007	
Entered By: Sherepta Mcleod		Entry Time: 17-09-2007 15:08:05	
		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: 13-03-2007	
Entered By: Sherepta Mcleod		Entry Time: 17-09-2007 15:08:05	
		Last Modification Time:	
		Page number: 53	
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 22		Section Date: 13-03-2007	
Entered By: Sherepta Mcleod		Entry Time: 17-09-2007 15:08:05	
		Last Modification Time:	

# CRF Report for Study E6270229

Patient: 1002

CRF: Week 22

Visit: WEEK 22

Site: CB\_001

Blank? Y

Visit Date: 13-03-2007

Investigator: C2474\_138

CRF Page #: 22

Document #: R156917313

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: 13-03-2007

Entered By: Sherepta Mcleod

Entry Time: 17-09-2007 15:08:05

Last Modification Time:

Page number: 54

## STUDY PRODUCT DISPENSATION

Actual Time

Product Dispensed

Flavor

Amount Dispensed

# CRF Report for Study E6270229

Patient: 1002	Site: CB_001	Investigator: C2474_138
CRF: Week 24 (Eos)	Blank? N	CRF Page #: 23
Visit: WEEK 24 (EOS)	Visit Date: 13-03-2007	Document #: R139455913
Entered By: Sherepta Mcleod	Entry Time: 25-04-2007 15:16:37	CRF Status: Entry Complete
Discrepancies: Closed	Modification Time: 21-11-2007 10:50:02	
Approval Status: Not Approved	Approval Time:	Approver:
Verification: Not Verified	Verification Time:	Verifier:
Comment:		

Section: Pro_Questionnaire	1 of 12	Blank? N	Section Status: Entry Complete
Visit: WEEK 24 (EOS)		Section Date: 13-03-2007	
Entered By: Sherepta Mcleod		Entry Time: 25-04-2007 15:16:37	
		Last Modification Time: 25-04-2007 15:27:26	
		Page number: 55	
PRO QUESTIONNAIRES			
Date	1.	With the possible exception of urinating, did subject complete Smoker Routine Questionnaire PRIOR to any study procedures being performed?	YES / NO
13-03-2007			YES

Section: Urine_Drug	2 of 12	Blank? N	Section Status: Entry Complete
Visit: WEEK 24 (EOS)		Section Date: 13-03-2007	
Entered By: Sherepta Mcleod		Entry Time: 25-04-2007 15:16:37	
		Last Modification Time: 25-04-2007 15:27:26	
		Page number: 55	
Drug Screen			
Date		Drug Screen Result	
13-03-2007		NEG	

Section: Alcohol_Screen	3 of 12	Blank? N	Section Status: Entry Complete
Visit: WEEK 24 (EOS)		Section Date: 13-03-2007	
Entered By: Sherepta Mcleod		Entry Time: 25-04-2007 15:16:37	
		Last Modification Time: 25-04-2007 15:27:26	
		Page number: 55	
Alcohol Screen			
Date		Breathalyzer Result	
13-03-2007		NEG	

Section: Preg_Test	4 of 12	Blank? N	Section Status: Entry Complete
Visit: WEEK 24 (EOS)		Section Date: 13-03-2007	
Entered By: Sherepta Mcleod		Entry Time: 25-04-2007 15:16:37	
		Last Modification Time: 25-04-2007 15:27:26	
		Page number: 55	



# CRF Report for Study E6270229

Patient: 1002

CRF: Week 24 (Eos)

Visit: WEEK 24 (EOS)

Site: CB\_001

Blank? N

Visit Date: 13-03-2007

Investigator: C2474\_138

CRF Page #: 23

Document #: R139455913

Section: Preg\_Test

4 of 12

Pregnancy Test

Date

13-03-2007

Result

N/A,  
MALE  
OR  
FEMA  
LE

Section: Urine\_Coll

5 of 12

Blank? N

Section Status: Entry Complete

Visit: WEEK 24 (EOS)

Section Date: 13-03-2007

Entered By: Sherepta Mcleod

Entry Time: 25-04-2007 15:16:37

Last Modification Time: 25-04-2007 15:27:26

Page number: 55

24-Hour Urine Collection

Scheduled Timepoint	Start Date	Start Time	Stop Date	Stop Time	Total Volume	Comments
SPOT URINE VOID	13-03-2007	UNK	13-03-2007	UNK	UNK	
0 HOUR TO 24 HOURS	13-03-2007	ND	13-03-2007	ND	ND	

Section: ECG

6 of 12

Blank? N

Section Status: Entry Complete

Visit: WEEK 24 (EOS)

Section Date: 13-03-2007

Entered By: Sherepta Mcleod

Entry Time: 25-04-2007 15:16:37

Last Modification Time: 25-04-2007 15:27:26

Page number: 56

12-LEAD ELECTROCARDIOGRAM REPORT

Actual Time

1055

Ventricular Heart Rate

82

Cardiac Cycle Measurements

PR Interval

138

QRS Duration

100

QT Interval

362

QTc Interval

400

ECG INTERPRETATION:

NORMAL

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: 13-03-2007

Entered By: Sherepta Mcleod

Entry Time: 25-04-2007 15:16:37

Last Modification Time: 17-09-2007 15:11:50

Page number: 57

# CRF Report for Study E6270229

Patient: 1002  
CRF: Week 24 (Eos)  
Visit: WEEK 24 (EOS)

Site: CB\_001  
Blank? N  
Visit Date: 13-03-2007

Investigator: C2474\_138  
CRF Page #: 23  
Document #: R139455913

Section: Hdyf_Oral_Health		7 of 12	
HDYF? / ORAL HEALTH QUESTIONS INQUIRY			
Date	Actual Time	HDYF Performed?	Oral Health Questions Performed? Comments
13-03-2007	NR	YES	YES

Section: Vital		8 of 12		Blank? N		Section Status: Entry Complete	
Visit: WEEK 24 (EOS)		Section Date: 13-03-2007		Entry Time: 25-04-2007 15:16:37		Last Modification Time: 21-11-2007 10:50:02	
Entered By: Sherepta Mcleod		Page number: 57					
VITAL SIGNS							
		Blood Pressure				Oral	
Date	Actual Time	Systolic	Diastolic	Pulse	Respiratory Rate	Temperature	Unit
13-03-2007	1045	138	79	63	14	ND	ND
						xxx.x	
Comments							

Section: Oral_Health_Exam		9 of 12		Blank? N		Section Status: Entry Complete	
Visit: WEEK 24 (EOS)		Section Date: 13-03-2007		Entry Time: 25-04-2007 15:16:37		Last Modification Time: 24-10-2007 12:33:00	
Entered By: Sherepta Mcleod		Page number: 57					
ORAL HEALTH EXAMINATION							
Date	Procedure			Relevant Findings?*		Findings	
13-03-2007	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: 13-03-2007		Entry Time: 25-04-2007 15:16:37		Last Modification Time: 25-04-2007 15:27:26	
Entered By: Sherepta Mcleod		Page number: 58					
PHYSICAL EXAMINATION							
Date							

# CRF Report for Study E6270229

Patient: 1002

CRF: Week 24 (Eos)

Visit: WEEK 24 (EOS)

Site: CB\_001

Blank? N

Visit Date: 13-03-2007

Investigator: C2474\_138

CRF Page #: 23

Document #: R139455913

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

Section: Weight_Height	11 of 12	Blank? N	Section Status: Entry Complete
Visit: WEEK 24 (EOS)		Section Date: 13-03-2007	
Entered By: Sherepta Mcleod		Entry Time: 25-04-2007 15:16:37	
		Last Modification Time: 25-04-2007 15:27:26	
		Page number: 58	
WEIGHT & HEIGHT			
Date	Weight	Unit	Height Unit
13-03-2007	61.0	KG	170 CM
	xxx.x		xxx.x

Section: Lab_Eval	12 of 12	Blank? N	Section Status: Entry Complete
Visit: WEEK 24 (EOS)		Section Date: 13-03-2007	
Entered By: Sherepta Mcleod		Entry Time: 25-04-2007 15:16:37	
	Last Modification Time: 25-04-2007 15:27:26		
	Page number: 59		
Laboratory Evaluations			
Date			
13-03-2007			
Were the scheduled laboratory samples obtained?	YES	No, specify	
Requisition Number 1	N527977		
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: 1002	Site: CB_001	Investigator: C2474_138
CRF: Week 24-2 (Eos)	Blank? N	CRF Page #: 24
Visit: WEEK 24 (EOS)	Visit Date: 13-03-2007	Document #: R139459913
Entered By: Sherepta Mcleod	Entry Time: 25-04-2007 15:27:27	CRF Status: Entry Complete
Discrepancies: None	Modification Time: 21-11-2007 11:05:14	
Approval Status: Not Approved	Approval Time:	Approver:
Verification: Not Verified	Verification Time:	Verifier:
Comment:		

Section: Pk_Blood_Biomark	1 of 11	Blank? N	Section Status: Entry Complete						
Visit: WEEK 24 (EOS)		Section Date: 13-03-2007							
Entered By: Sherepta Mcleod		Entry Time: 25-04-2007 15:27:27							
		Last Modification Time: 17-09-2007 15:18:12							
		Page number: 59							
<p>Blood Sampling For Biomarkers/Chemistry/Hematology (following an overnight fast)</p> <table border="1"> <thead> <tr> <th>Date</th> <th>Actual Time</th> <th>Comments</th> </tr> </thead> <tbody> <tr> <td>13-03-2007</td> <td>1130</td> <td>SAFETY LABS ONLY, NO BIOMARKERS DONE</td> </tr> </tbody> </table>				Date	Actual Time	Comments	13-03-2007	1130	SAFETY LABS ONLY, NO BIOMARKERS DONE
Date	Actual Time	Comments							
13-03-2007	1130	SAFETY LABS ONLY, NO BIOMARKERS DONE							

Section: Expired_Carbon_M	2 of 11	Blank? N	Section Status: Entry Complete										
Visit: WEEK 24 (EOS)		Section Date: 13-03-2007											
Entered By: Sherepta Mcleod		Entry Time: 25-04-2007 15:27:27											
		Last Modification Time: 25-04-2007 16:01:35											
		Page number: 59											
<p>EXPIRED CARBON MONOXIDE</p> <table border="1"> <thead> <tr> <th>Date</th> <th>Actual Time</th> <th>ECO Level (ppm)</th> <th>%COHb</th> <th>Comments</th> </tr> </thead> <tbody> <tr> <td>13-03-2007</td> <td>1042</td> <td>21</td> <td>3.9</td> <td></td> </tr> </tbody> </table>				Date	Actual Time	ECO Level (ppm)	%COHb	Comments	13-03-2007	1042	21	3.9	
Date	Actual Time	ECO Level (ppm)	%COHb	Comments									
13-03-2007	1042	21	3.9										

Section: Blood_Sampl_Cohb	3 of 11	Blank? N	Section Status: Entry Complete						
Visit: WEEK 24 (EOS)		Section Date: 13-03-2007							
Entered By: Sherepta Mcleod		Entry Time: 25-04-2007 15:27:27							
		Last Modification Time: 17-09-2007 15:20:12							
		Page number: 59							
<p>Blood Sampling for %COHb</p> <table border="1"> <thead> <tr> <th>Date</th> <th>Actual Time</th> <th>Comments</th> </tr> </thead> <tbody> <tr> <td>13-03-2007</td> <td>1130</td> <td></td> </tr> </tbody> </table>				Date	Actual Time	Comments	13-03-2007	1130	
Date	Actual Time	Comments							
13-03-2007	1130								

Section: Pre_Bronch_Spir	4 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 24 (EOS)		Section Date: 13-03-2007	
Entered By: Sherepta Mcleod		Entry Time: 25-04-2007 15:27:27	
		Last Modification Time: 21-11-2007 10:58:28	

# CRF Report for Study E6270229

Patient: 1002

CRF: Week 24-2 (Eos)

Visit: WEEK 24 (EOS)

Site: CB\_001

Blank? N

Visit Date: 13-03-2007

Investigator: C2474\_138

CRF Page #: 24

Document #: R139459913

Section: Pre_Bronch_Spir		4 of 11		Page number: 60			
PRE-BRONCHODILATOR BEST BASELINE SPIROMETRY TEST RESULT							
Actual Time of FEV1/FVC							
Date	Test	Testing Position	FEV1 L	FEV1 Predicted (%)	FVC L	FVC Predicted (%)	Comments
13-03-2007	1123	STANDI NG	4.16	104	5.11	104	

Section: Proventil_Admin		5 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 24 (EOS)		Section Date: 13-03-2007		Entry Time: 25-04-2007 15:27:27			
Entered By: Sherepta Mcleod		Last Modification Time: 25-04-2007 16:01:35		Page number: 60			
PROVENTIL ADMINISTRATION							
Actual Time of Proventil Administration							
Date	Administration	Amount Administered				Comments	
13-03-2007	1124	2 METERED PUFFS					

Section: Post_Bronch_Spir		6 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 24 (EOS)		Section Date: 13-03-2007		Entry Time: 25-04-2007 15:27:27			
Entered By: Sherepta Mcleod		Last Modification Time: 21-11-2007 11:05:14		Page number: 60			
POST-BRONCHODILATOR BEST SPIROMETRY TEST RESULT							
Actual Time of FEV1/FVC							
Date	Test	Testing Position	FEV1 L	FEV1 Predicted (%)	FVC L	FVC Predicted (%)	Comments
13-03-2007	1139	STANDING	4.27	107	5.54	113	

Section: Used_Study_Tobac		7 of 11		Blank? Y		Section Status: Entry Complete	
Visit: WEEK 24 (EOS)		Section Date: 13-03-2007		Entry Time: 25-04-2007 15:27:27			
Entered By: Sherepta Mcleod		Last Modification Time: 13-09-2007 10:11:19		Page number: 61			
USED STUDY TOBACCO-HEATING CIGARETTE COLLECTION							
				Number of Study Tobacco-Heating		Weight of	

# CRF Report for Study E6270229

Patient: 1002

CRF: Week 24-2 (Eos)

Visit: WEEK 24 (EOS)

Site: CB\_001

Blank? N

Visit Date: 13-03-2007

Investigator: C2474\_138

CRF Page #: 24

Document #: R139459913

Section: Used_Study_Tobac		7 of 11							
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: Entry Complete				
Visit: WEEK 24 (EOS)		Section Date: 13-03-2007					
Entered By: Sherepta Mcleod		Entry Time: 25-04-2007 15:27:27					
		Last Modification Time: 21-11-2007 11:01:55					
		Page number: 62					
USED STUDY SNUS COLLECTION							
Scheduled Collection			Number of Study	Any Product	If Yes, # of		
Timepoint	Start Date	Start Time	Stop Date	Stop Time	Pouches Collected	Deviation?	other brand: Comments

Section: Used_Study_Burn	9 of 11	Blank? Y	Section Status: Entry Complete				
Visit: WEEK 24 (EOS)		Section Date: 13-03-2007					
Entered By: Sherepta Mcleod		Entry Time: 25-04-2007 15:27:27					
		Last Modification Time: 13-09-2007 10:11:19					
		Page number: 63					
USED STUDY TOBACCO-BURNING CIGARETTE COLLECTION							
Scheduled Collection			Number of Study Tobacco-	Any Product	If Yes, # of other		
Timepoint	Start Date	Start Time	Stop Date	Stop Time	Burning Cigarettes Collected	Deviation?	brand: Comments

Section: Used_Butt_Measur	10 of 11	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)		Section Date: 13-03-2007	
Entered By: Sherepta Mcleod		Entry Time: 25-04-2007 15:27:27	
		Last Modification Time: 13-09-2007 10:09:14	
		Page number: 64	
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 24 (EOS)		Section Date: 13-03-2007	
Entered By: Sherepta Mcleod		Entry Time: 25-04-2007 15:27:27	
		Last Modification Time: 13-09-2007 10:09:14	
		Page number: 65	

# CRF Report for Study E6270229

Patient: 1002

CRF: Week 24-2 (Eos)

Visit: WEEK 24 (EOS)

Site: CB\_001

Blank? N

Visit Date: 13-03-2007

Investigator: C2474\_138

CRF Page #: 24

Document #: R139459913

Section: Used\_Butt\_Measur 11 of 11

## USUAL STUDY TOBACCO-BURNING CIGARETTE BUTT MEASUREMENT

Scheduled Collection

Date

Period

Cigarette Butt Number

Cigarette Butt Measurement (mm)

# CRF Report for Study E6270229

Patient: 1002	Site: CB_001	Investigator: C2474_138
CRF: Week 24-3	Blank? N	CRF Page #: 25
Visit: WEEK 24 (EOS)	Visit Date: 13-03-2007	Document #: R139479613
Entered By: Sherepta Mcleod	Entry Time: 25-04-2007 16:01:39	CRF Status: Entry Complete
Discrepancies: Active	Modification Time: 21-11-2007 12:19:38	
Approval Status: Not Approved	Approval Time:	Approver:
Verification: Not Verified	Verification Time:	Verifier:
Comment:		

Section: Unused_Study_Pro		Blank? N		Section Status: Entry Complete	
Visit: WEEK 24 (EOS)		Section Date: 13-03-2007			
Entered By: Sherepta Mcleod		Entry Time: 25-04-2007 16:01:39			
		Last Modification Time: 21-11-2007 11:00:45			
		Page number: 65A			
Unused Study Product Returned					
				Amount Returned	
Date	Actual Time	Product Returned	Flavor	Packs	Individual Cigarettes / pouches
13-03-2007	NR	SNUS	ORIGINAL	0	0
13-03-2007	NR	<b>SNUS</b>	<b>FROST</b>	0	0



# CRF Report for Study E6270229

Patient: 1002  
CRF: Precon\_Med  
Visit: PRECON\_MEDS  
Entered By: Sherepta Mcleod  
Discrepancies: None  
Approval Status: Not Approved  
Verification: Not Verified  
Comment:

Site: CB\_001  
Blank? N  
Visit Date: 31-01-2007  
Entry Time: 25-04-2007 16:03:27  
Modification Time: 25-04-2007 16:04:02  
Approval Time:  
Verification Time:

Investigator: C2474\_138  
CRF Page #: 26  
Document #: R139480513  
CRF Status: Entry Complete  
Approver:  
Verifier:

Section: Pre_Conmed	Blank? N	Section Status: Entry Complete
Visit: PRECON_MEDS	Section Date: 31-01-2007	
Entered By: Sherepta Mcleod	Entry Time: 25-04-2007 16:03:27	
	Last Modification Time: 25-04-2007 16:04:02	
	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?									
NO									
Seq #	Drug Name	Indication	Dose / Dose Unit	Route	Specify	Freq	Specify	Start Date	Stop Date/Ongoing

# CRF Report for Study E6270229

Patient: 1002	Site: CB_001	Investigator: C2474_138
CRF: AE	Blank? N	CRF Page #: 27
Visit: AE	Visit Date: 09-02-2007	Document #: R139480713
Entered By: Sherepta Mcleod	Entry Time: 25-04-2007 16:04:03	CRF Status: Entry Complete
Discrepancies: None	Modification Time: 17-09-2007 15:27:00	
Approval Status: Not Approved	Approval Time:	Approver:
Verification: Not Verified	Verification Time:	Verifier:
Comment:		

Section: Ae_Med		Blank? N		Section Status: Entry Complete							
Visit: AE		Section Date: 09-02-2007									
Entered By: Sherepta Mcleod		Entry Time: 25-04-2007 16:04:03									
		Last Modification Time: 17-09-2007 15:27:00									
		Page number: 67									
Adverse Events											
Did the subject experience any adverse events? NO											
Event No.	Adverse Event	Onset Date	Time	Resolved/Changed Date	Time	Serious Event?	Severity	Relationship to Product	Relationship to Procedure	Action Taken	Outcome to Date

# CRF Report for Study E6270229

Patient: 1002	Site: CB_001	Investigator: C2474_138
CRF: Ecg_Unscheduled	Blank? Y	CRF Page #: 28
Visit: ECG_UNSCHEDED	Visit Date: 00-00-	Document #: R167250613
Entered By: Sherepta Mcleod	Entry Time: 21-11-2007 11:06:58	CRF Status: Created
Discrepancies: None	Modification Time:	
Approval Status: Not Approved	Approval Time:	Approver:
Verification: Not Verified	Verification Time:	Verifier:
Comment:		

Section: ECG	Blank? Y	Section Status: Created
Visit: ECG_UNSCHEDED	Section Date: 00-00-	
Entered By: Sherepta Mcleod	Entry Time: 21-11-2007 11:06:58	
Last Modification Time:		
Page number: 68		
UNSCHEDULED 12-LEAD ELECTROCARDIOGRAM REPORT		
Ventricular Cardiac Cycle Measurements		
Date	Actual Time	Heart Rate PR Interval QRS Duration QT Interval QTc Interval Interpretation Comments

# CRF Report for Study E6270229

Patient: 1002 Site: CB\_001 Investigator: C2474\_138  
CRF: Lab\_Unscheduled Blank? Y CRF Page #: 29  
Visit: LAB\_UNSCHEDED Visit Date: 00-00- Document #: R167250713  
Entered By: Sherepta Mcleod Entry Time: 21-11-2007 11:07:05 CRF Status: Created  
Discrepancies: None Modification Time:  
Approval Status: Not Approved Approval Time:  
Verification: Not Verified Verification Time:  
Comment: Approver:  
Verifier:

Section: Lab_Eval	Blank? Y	Section Status: Created
Visit: LAB_UNSCHEDED	Section Date: 00-00-	
Entered By: Sherepta Mcleod	Entry Time: 21-11-2007 11:07:05	
	Last Modification Time:	
	Page number: 69	

Unscheduled Laboratory Evaluations							
Date	Requisition Number	Clinically Significant?	Test Name	High(H)/Low(L)	Lab ID	Lab Name	Comments

# CRF Report for Study E6270229

Patient: 1002  
CRF: Vital\_Unscheduled  
Visit: VITAL\_UNSCHEDED  
Entered By: Sherepta Mcleod  
Discrepancies: None  
Approval Status: Not Approved  
Verification: Not Verified  
Comment:

Site: CB\_001  
Blank? Y  
Visit Date: 00-00-  
Entry Time: 21-11-2007 11:07:10  
Modification Time:  
Approval Time:  
Verification Time:

Investigator: C2474\_138  
CRF Page #: 30  
Document #: R167250913  
CRF Status: Created

Approver:  
Verifier:

Section: Vital		Blank? Y		Section Status: Created			
Visit: VITAL_UNSCHEDED		Section Date: 00-00-					
Entered By: Sherepta Mcleod		Entry Time: 21-11-2007 11:07:10					
		Last Modification Time:					
		Page number: 70					
UNSCHEDULED VITAL SIGNS							
Date	Actual Time	Blood Pressure Systolic Diastolic	Pulse	Respiratory Rate	Oral Temperature xxx.x	Unit	Comments

# CRF Report for Study E6270229

Patient: 1002	Site: CB_001	Investigator: C2474_138
CRF: Stdy_Prdt_Dis_Unschedulec	Blank? Y	CRF Page #: 31
Visit: STDY_PRDT_UNSCHE	Visit Date: 00-00-	Document #: R167251013
Entered By: Sherepta Mcleod	Entry Time: 21-11-2007 11:07:15	CRF Status: Created
Discrepancies: None	Modification Time:	
Approval Status: Not Approved	Approval Time:	Approver:
Verification: Not Verified	Verification Time:	Verifier:
Comment:		

Section: Study_Prod_Dispe	Blank? Y	Section Status: Created
Visit: STDY_PRDT_UNSCHE	Section Date: 00-00-	
Entered By: Sherepta Mcleod	Entry Time: 21-11-2007 11:07:15	
	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: 1002  
CRF: Expired\_Co2\_Unscheduled  
Visit: EXPIRED\_CO2\_UNSC  
Entered By: Sherepta Mcleod  
Discrepancies: None  
Approval Status: Not Approved  
Verification: Not Verified  
Comment:

Site: CB\_001  
Blank? Y  
Visit Date: 00-00-  
Entry Time: 21-11-2007 11:07:22  
Modification Time:  
Approval Time:  
Verification Time:

Investigator: C2474\_138  
CRF Page #: 32  
Document #: R167251213  
CRF Status: Created

Approver:  
Verifier:

Section: Expired\_Carbon\_M  
Visit: EXPIRED\_CO2\_UNSC  
Entered By: Sherepta Mcleod

Blank? Y  
Section Date: 00-00-  
Entry Time: 21-11-2007 11:07:22  
Last Modification Time:  
Page number: 72

Section Status: Created

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

# CRF Report for Study E6270229

Patient: 1002

CRF: Oral\_Health\_Unscheduled

Visit: ORAL\_HEALTH\_UNSC

Entered By: Sherepta Mcleod

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CB\_001

Blank? Y

Visit Date: 00-00-

Entry Time: 21-11-2007 11:07:34

Modification Time:

Approval Time:

Verification Time:

Investigator: C2474\_138

CRF Page #: 33

Document #: R167251413

CRF Status: Created

Approver:

Verifier:

Section: Oral_Health_Exam		Blank? Y	Section Status: Created	
Visit: ORAL_HEALTH_UNSC		Section Date: 00-00-		
Entered By: Sherepta Mcleod		Entry Time: 21-11-2007 11:07:34		
		Last Modification Time:		
		Page number: 73		
UNSCHEDULED ORAL HEALTH EXAMINATION				
Date	Actual Time	Code	Relevant Findings?	Comment



# CRF Report for Study E6270229

Patient: 1002 Site: CB\_001 Investigator: C2474\_138  
CRF: Spirometry\_Unscheduled Blank? Y CRF Page #: 34  
Visit: SPIRO\_TEST\_UNSCH Visit Date: 00-00- Document #: R167251613  
Entered By: Sherepta Mcleod Entry Time: 21-11-2007 11:07:38 CRF Status: Created  
Discrepancies: None Modification Time:  
Approval Status: Not Approved Approval Time:  
Verification: Not Verified Verification Time:  
Comment: Approver:  
Verifier:

Section: Pre_Bronch_Spir	Blank? Y	Section Status: Created
Visit: SPIRO_TEST_UNSCH	Section Date: 00-00-	
Entered By: Sherepta Mcleod	Entry Time: 21-11-2007 11:07:38	
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 Predicted (%)	FEV1 L	FVC Predicted (%)	FVC L	Comments

# CRF Report for Study E6270229

Patient: 1002  
CRF: Study\_Completion  
Visit: STUDY\_COMP  
Entered By: Sherepta Mcleod  
Discrepancies: Closed  
Approval Status: Not Approved  
Verification: Not Verified  
Comment:

Site: CB\_001  
Blank? N  
Visit Date: 13-03-2007  
Entry Time: 17-09-2007 15:27:09  
Modification Time: 18-09-2007 09:07:10  
Approval Time:  
Verification Time:

Investigator: C2474\_138  
CRF Page #: 35  
Document #: R156919913  
CRF Status: Entry Complete  
Approver:  
Verifier:

Section: Study_Comp	Blank? N	Section Status: Entry Complete
Visit: STUDY_COMP	Section Date: 13-03-2007	
Entered By: Sherepta Mcleod	Entry Time: 17-09-2007 15:27:09	
	Last Modification Time: 17-09-2007 15:27:59	
	Page number: 75	

Study Completion	
Did the subject complete the study?	NO
Date the subject completed OR withdrew from the study:	13-03-2007
Reason for Withdrawal	CONSENT
Specify	MOVED OUT OF TOWN
Investigator Comments	Bryan C. Pogue, M.D.
Principal Investigator	Date

DEC 07 2007

Study No. 207268 / Protocol No. 6270-229

## Screening Lab Tests Results

### Urine Drug Screen, Urine Dipstick, Urine Pregnancy Test, and Alcohol Breath Test

Page 1 of 2

(b) (6)	Screening # <u>1008</u>
Date of Test: <u>31 Jan 2007</u> (dd/mm/yyyy)	

Time collected: 1319 KM 1:31:07  
Temperature: 94°F KM 1:31:07

#### Urine Dipstick – Adulta Check® 6

Lot# 070704 Exp. Date: 07/09

Time of Urine Application (24 hour clock)	Oxidants Read between 15-30 seconds	Creatinine Read between 30-60 seconds	Nitrite Read Immediately	Glutaraldehyde Read immediately	pH Read immediately	Chromate Read immediately	Staff Init
1321	neg	50	neg	neg	5.0	neg	KM

#### Urine Drug Screen – EZ Split Key™

Lot# <sup>607</sup>DOA50521 Exp. Date: 2008/04  
KM 1:31:07

Time of Key Insertion (24 hour clock)	Staff Init	AMP	COC	THC	mAMP	OPI	PCP	BZO	BAR	MTD	MDMA	Time Result Recorded (24 hour clock)	Staff Init
1320	KM	<input type="checkbox"/> pos <input checked="" type="checkbox"/> neg	<input type="checkbox"/> pos <input checked="" type="checkbox"/> neg	<input type="checkbox"/> pos <input checked="" type="checkbox"/> neg	<input type="checkbox"/> pos <input checked="" type="checkbox"/> neg	<input type="checkbox"/> pos <input checked="" type="checkbox"/> neg	<input type="checkbox"/> pos <input checked="" type="checkbox"/> neg	<input type="checkbox"/> pos <input checked="" type="checkbox"/> neg	<input type="checkbox"/> pos <input checked="" type="checkbox"/> neg	<input type="checkbox"/> pos <input checked="" type="checkbox"/> neg	<input type="checkbox"/> pos <input checked="" type="checkbox"/> neg	1325	KM

## Study No. 207268 / Protocol No. 6270-229 Screening Lab Tests Results

Document Version Date: 17-Jan-2007

Page 2 of 2

### Breath Alcohol Test

Time Test Performed (24 hour clock): 12:50

Brand: LIFELOC Model or Lot#: XC-FA-0001 Exp. Date (if disposable test): N/A

Calibration Cannister Brand(if using a digital device) and Exp date: \_\_\_\_\_

Test Results (from digital display)	Is Test Result Within Acceptable Range?	Time of results (24 hr. clock)	Staff Init
<u>0.00</u>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<u>1250</u>	<u>+</u>

### Urine Pregnancy Test - n/a male KM 1-31-07

Brand: \_\_\_\_\_ Lot# \_\_\_\_\_ Exp. Date: \_\_\_\_\_

Test Results	Time of Results (24 hour clock)	Staff Init
<input type="checkbox"/> positive <input type="checkbox"/> negative		

Investigator Results Review: \_\_\_\_\_

Signature

Date

**Covance CLS**

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

**LABORATORY REPORT**

ACCESSION NO. N526679

Page 1 of 3

INVESTIGATOR: (B17173)

Bryan Pogue, M.D.  
c/o Sherepta Mcleod  
6565 W Emerald St.  
Boise, ID United States 83704

PROTOCOL 6270-229

INVESTIGATOR NO.: 1

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

SPONSOR REPORT TO:

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

Screen

COLLECTION TIME:13:43 DATE:31-Jan-2007

DATE RECEIVED IN LABORATORY: 01-Feb-2007

DATE REPORTED BY LABORATORY: 01-Feb-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S1008

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

**CHEMISTRY PANEL**

Total Bili	0.6	0.2-1.2 mg/dL
Alk Phos	62	31-129 U/L
ALT (SGPT)	10	6-43 U/L
AST (SGOT)	21	11-36 U/L
GGT	14	10-61 U/L
LDH	145	53-234 U/L
Urea Nitr	13	4-24 mg/dL
Creatinine	0.9	0.5-1.2 mg/dL
Glucose	86	70-115 mg/dL
Uric Acid	4.6	2.1-8.2 mg/dL
Calcium	9.8	8.3-10.6 mg/dL
Phosphorus	3.2	2.2-5.1 mg/dL
Total Prot	7.0	6.1-8.4 g/dL
Albumin	4.5	3.3-4.9 g/dL
Sodium	140	132-147 mEq/L
Potassium	3.7	3.4-5.4 mEq/L
Chloride	101	94-112 mEq/L

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

B17173

(INV)

**Covance CLS**

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

**LABORATORY REPORT**

ACCESSION NO. N526679

Page 2 of 3

INVESTIGATOR: (B17173)

Bryan Pogue, M.D.  
c/o Sherepta Mcleod  
6565 W Emerald St.  
Boise, ID United States 83704

PROTOCOL 6270-229

INVESTIGATOR NO.: 1

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

SPONSOR REPORT TO:

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

Screen

COLLECTION TIME:13:43 DATE:31-Jan-2007

DATE RECEIVED IN LABORATORY: 01-Feb-2007

DATE REPORTED BY LABORATORY: 01-Feb-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S1008

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

**HEMATOLOGY& DIFFERENTIAL PANEL**

HGB	15.1	12.7-18.1 g/dL
HCT	42	39-54 %
RBC	4.9	4.5-6.4x10 <sup>6</sup> /uL
MCV	85	79-96 fL
MCH	31	26-34 pg
MCHC	36	31-38 g/dL
RDW	12.4	12.0-15.0 %
RBC Morph	Normocytic	
WBC	7.45	3.80-10.70 x10 <sup>3</sup> /uL
Neutrophil	4.71	1.96-7.23 x10 <sup>3</sup> /uL
Lymphocyte	2.17	0.91-4.28 x10 <sup>3</sup> /uL
Monocytes	0.41	0.12-0.92 x10 <sup>3</sup> /uL
Eosinophil	0.04	0.00-0.57 x10 <sup>3</sup> /uL
Basophils	0.12	0.00-0.20 x10 <sup>3</sup> /uL
Neutrophil	63.3	40.5-75.0 %
Lymphocyte	29.0	15.4-48.5 %
Monocytes	5.5	2.6-10.1 %
Eosinophil	0.5	0.0-6.8 %
Basophils	1.6	0.0-2.0 %
Platelets	214	140-400 x10 <sup>3</sup> /uL

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

B17173

(INV)

**Covance CLS**

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

**LABORATORY REPORT**

ACCESSION NO. N526679

Page 3 of 3

## INVESTIGATOR: (B17173)

Bryan Pogue, M.D.  
c/o Sherepta Mcleod  
6565 W Emerald St.  
Boise, ID United States 83704

PROTOCOL 6270-229

INVESTIGATOR NO.: 1

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

## SPONSOR REPORT TO:

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

Screen

COLLECTION TIME:13:43 DATE:31-Jan-2007

DATE RECEIVED IN LABORATORY: 01-Feb-2007

DATE REPORTED BY LABORATORY: 01-Feb-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S1008

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

## URINE MACRO &amp; MICRO PANEL

Color Yellow

Ref Rng:

Colorless or Yellow

Clarity Clear

Ref Rng:Clear

Spec Grav 1.009

1.003-1.035

pH 6.0

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

Nitrite Negative

Ref Rng:Negative

Leuk Est Negative

Ref Rng:Negative

Microscop Positive

## CELLULAR ELEMENTS


WBC 1

0-5 /HPF

## MICROORGANISMS

Bacteria Present

Ref Rng:Not present

  
Investigator Signature:  
Date:

H(High) or L(Low)-Values above or below Covance CLS reference range  
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PROTOCOL 6270-229

INVESTIGATOR NO.: 1

RANDOMIZATION NUMBER:

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SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S1008

Is this Clinically  
Significant/ Adverse  
Event?

Yes


No

TOTAL IRON

Total Iron 140 45-160 ug/dL

HEPATITIS A ANTIBODY-IGM

HepA IgMAb Negative No Ref Rng

  
Investigator Signature:2/5/07  
Date:

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



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DATE RECEIVED IN LABORATORY: 01-Feb-2007

DATE REPORTED BY LABORATORY: 01-Feb-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S1008

Is this Clinically  
Significant/ Adverse  
Event?

Yes


No

HIV 1/HIV 2 ANTIBODY SCREEN

HIV-1/2

Non-Reactive

Reference Range:  
Non-Reactive

  
Investigator Signature:  
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

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DATE RECEIVED IN LABORATORY: 01-Feb-2007

DATE REPORTED BY LABORATORY: 01-Feb-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S1008

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

  
Investigator Signature:

2/5/07  
Date:

B17173

(INV)

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**LABORATORY REPORT**

ACCESSION NO. N526679

Page 1 of 1

INVESTIGATOR: (B17173)

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PROTOCOL 6270-229

INVESTIGATOR NO.: 1

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

SPONSOR REPORT TO:

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

Screen

COLLECTION TIME:13:43 DATE:31-Jan-2007

DATE RECEIVED IN LABORATORY: 01-Feb-2007

DATE REPORTED BY LABORATORY: 02-Feb-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S1008

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

  
Investigator Signature:  
Date:

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**LABORATORY REPORT**

ACCESSION NO. N526679

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Boise, ID United States 83704

PROTOCOL 6270-229

INVESTIGATOR NO.: 1

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

SPONSOR REPORT TO:

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

Screen

COLLECTION TIME: 13:43 DATE: 31-Jan-2007

DATE RECEIVED IN LABORATORY: 01-Feb-2007

DATE REPORTED BY LABORATORY: 02-Feb-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S1008

Is this Clinically  
Significant/ Adverse  
Event?


Yes

No

HEPATITIS B CORE ANTIBODY-IGM

Hep Bc IgM Negative

Ref Rng: Negative

  
Investigator Signature:  
Date:

H(High) or L(Low): Values above or below Covance CLS reference range  
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B17173

(INV)

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Tel. +1 (800) 327 7270

**LABORATORY REPORT**

ACCESSION NO. N527948

Page 1 of 1

INVESTIGATOR: (B17173)

Bryan Pogue, M.D.  
c/o Sherepta Mcleod  
6565 W Emerald St.  
Boise, ID United States 83704

PROTOCOL 6270-229

INVESTIGATOR NO.: 1

RANDOMIZATION NUMBER: R1002

PATIENT INITIALS: (b) (6)

VISIT: 24 HR UR

SPONSOR REPORT TO:

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

24 Hr Urine Collection

COLLECTION TIME: 14:55 DATE: 13-Feb-2007

DATE RECEIVED IN LABORATORY: 16-Feb-2007

DATE REPORTED BY LABORATORY: 16-Feb-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S1008

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

URINE CREATININE, 24 HR

U24h Creat 1371

800-1800 mg/24hr

UAlq24Crea 76.8

mg/dL No Ref Rng

ELAPSED DATE AND TIME, 24HR

Elpsd D&amp;T 1452 min

24 HR COLLECTION INFORMATION

Start Date 13-Feb-2007

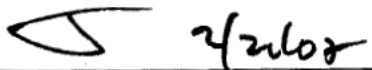
Start Time 14:55

Stop Date 14-Feb-2007

Stop Time 15:07

TOTAL 24HR URINE VOLUME

Total Vol. 1800 mL

  
Investigator Signature:

Date:

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B17173

(INV)

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

ACCESSION NO. N526699

Page 1 of 3

## INVESTIGATOR: (B17173)

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6565 W Emerald St.  
Boise, ID United States 83704

PROTOCOL 6270-229

INVESTIGATOR NO.: 1

RANDOMIZATION NUMBER: R1002

PATIENT INITIALS: (b) (6)

VISIT: 2

## SPONSOR REPORT TO:

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

Week 0

COLLECTION TIME: 06:58 DATE: 14-Feb-2007

DATE RECEIVED IN LABORATORY: 15-Feb-2007

DATE REPORTED BY LABORATORY: 16-Feb-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S1008

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

## CHEMISTRY PANEL

Total Bili	0.3	0.2-1.2 mg/dL
Alk Phos	68	31-129 U/L
ALT (SGPT)	13	6-43 U/L
AST (SGOT)	18	11-36 U/L
GGT	11	10-61 U/L
LDH	136	53-234 U/L
Urea Nitr	18	4-24 mg/dL
Creatinine	1.0	0.5-1.2 mg/dL
Glucose	98	70-115 mg/dL
Uric Acid	4.9	2.1-8.2 mg/dL
Calcium	9.8	8.3-10.6 mg/dL
Phosphorus	4.8	2.2-5.1 mg/dL
Total Prot	7.0	6.1-8.4 g/dL
Albumin	4.5	3.3-4.9 g/dL
Sodium	143	132-147 mEq/L
Potassium	4.0	3.4-5.4 mEq/L
Chloride	105	94-112 mEq/L

Investigator Signature:

Date:

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PROTOCOL 6270-229

INVESTIGATOR NO.: 1

RANDOMIZATION NUMBER: R1002

PATIENT INITIALS: (b) (6)

VISIT: 2

## SPONSOR REPORT TO:

Russell M. Dixon, MD  
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3402 Kinsman Boulevard  
Madison, WI United States 53704

Week 0

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DATE REPORTED BY LABORATORY: 16-Feb-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S1008

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

## HEMATOLOGY&amp; DIFFERENTIAL PANEL

HGB	15.2	12.7-18.1 g/dL
HCT	45	39-54 %
RBC	5.0	4.5-6.4x10 <sup>6</sup> /uL
MCV	90	79-96 fL
MCH	30	26-34 pg
MCHC	34	31-38 g/dL
RDW	13.0	12.0-15.0 %
RBC Morph	Normocytic	
WBC	7.73	3.80-10.70 x10 <sup>3</sup> /uL
Neutrophil	4.66	1.96-7.23 x10 <sup>3</sup> /uL
Lymphocyte	2.48	0.91-4.28 x10 <sup>3</sup> /uL
Monocytes	0.43	0.12-0.92 x10 <sup>3</sup> /uL
Eosinophil	0.10	0.00-0.57 x10 <sup>3</sup> /uL
Basophils	0.06	0.00-0.20 x10 <sup>3</sup> /uL
Neutrophil	60.3	40.5-75.0 %
Lymphocyte	32.1	15.4-48.5 %
Monocytes	5.5	2.6-10.1 %
Eosinophil	1.3	0.0-6.8 %
Basophils	0.8	0.0-2.0 %
Platelets	203	140-400 x10 <sup>3</sup> /uL

Investigator Signature:

Date:

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SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S1008

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

## URINE MACRO &amp; MICRO PANEL

Color Yellow

Ref Rng:  
Colorless or Yellow

Clarity Clear

Ref Rng:Clear

Spec Grav 1.013

1.003-1.035

pH 5.5

5.0-8.0

Protein Negative

Ref Rng:Negative

Glucose Normal

Ref Rng:Normal

Ketones Negative

Ref Rng:Negative

Bilirubin Negative

Ref Rng:Negative

Urobilin Normal

Ref Rng:Normal

Blood Negative

Ref Rng:Negative

Nitrite Negative

Ref Rng:Negative

Leuk Est Negative

Ref Rng:Negative

Microscop Positive

## CELLULAR ELEMENTS

WBC 1

0-5 /HPF

## MISCELLANEOUS ELEMENTS

Mucous Present

Ref Rng:Not present

Investigator Signature:

Date:

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

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PROTOCOL 6270-229

INVESTIGATOR NO.: 1

RANDOMIZATION NUMBER: R1002

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VISIT: 2

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DATE REPORTED BY LABORATORY: 16-Feb-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S1008

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

## TOTAL IRON

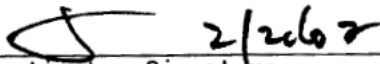
Total Iron 82 45-160 ug/dL

## C-REACTIVE PROTEIN

CRP-HS 0.024 <=0.287 mg/dL

## CARBOXYHEMOGLOBIN

Carboxyhem 7.7 % saturation  
No Ref Rng

  
Investigator Signature:

\_\_\_\_\_  
Date:

H(High) or L(Low)-Values above or below Covance CLS reference range  
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B17173

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PROTOCOL 6270-229

INVESTIGATOR NO.: 1

RANDOMIZATION NUMBER: R1002

PATIENT INITIALS: (b) (6)

VISIT: 2

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SCREENING NUMBER: S1008

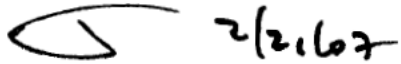
Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

## FIBRINOGEN

Fibrinogen 239 200-400 mg/dL

  
Investigator Signature:

Date:

H(High) or L(Low): Values above or below Covance CLS reference range  
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PROTOCOL 6270-229

INVESTIGATOR NO.: 1

RANDOMIZATION NUMBER: R1002

PATIENT INITIALS: (b) (6)

VISIT: 2

SPONSOR REPORT TO:

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

Week 0

COLLECTION TIME: 06:58 DATE: 14-Feb-2007

DATE RECEIVED IN LABORATORY: 15-Feb-2007

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SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S1008

Is this Clinically  
Significant/ Adverse  
Event?

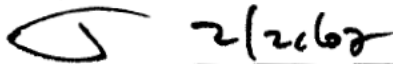
Yes

No

URINE CREATININE, SPOT

Rnd Ur Crt 91

mg/dL No Ref Rng

  
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

B17173

(INV)

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Boise, ID United States 83704

PROTOCOL 6270-229

INVESTIGATOR NO.: 1

RANDOMIZATION NUMBER: R1002

PATIENT INITIALS: (b) (6)

VISIT: 2

SPONSOR REPORT TO:

Russell M. Dixon, MD  
Medical Director  
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Week 0

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SCREENING NUMBER: S1008

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Significant/ Adverse  
Event?

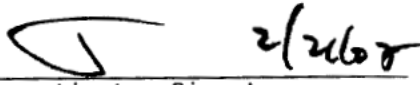
Yes

No

HAS PATIENT FASTED 8 HOURS?

Fasted?

Yes

  
Investigator Signature:

Date:

B17173

(INV)

**Covance CLS**

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**LABORATORY REPORT**

ACCESSION NO. N526699

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Bryan Pogue, M.D.  
c/o Sherepta Mcleod  
6565 W Emerald St.  
Boise, ID United States 83704

PROTOCOL 6270-229

INVESTIGATOR NO.: 1

RANDOMIZATION NUMBER: R1002

PATIENT INITIALS: (b) (6)

VISIT: 2

SPONSOR REPORT TO:

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

Week 0

COLLECTION TIME:06:58 DATE:14-Feb-2007

DATE RECEIVED IN LABORATORY: 15-Feb-2007

DATE REPORTED BY LABORATORY: 12-Mar-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S1008

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

HOMOCYSTEINE

Homocys

9.63

5.90-16.00 umol/L



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

B17173

(INV)

**Covance CLS**

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

**LABORATORY REPORT**

ACCESSION NO. N526699

Page 1 of 1

INVESTIGATOR: (B17173)

Bryan Pogue, M.D.

c/o Sherepta Mcleod

6565 W Emerald St.

Boise, ID United States 83704

PROTOCOL 6270-229

INVESTIGATOR NO.: 1

RANDOMIZATION NUMBER: R1002

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

SPONSOR REPORT TO:

Russell M. Dixon, MD

Medical Director

Covance CRU, Inc.

3402 Kinsman Boulevard

Madison, WI United States 53704

COLLECTION TIME: 06:58 DATE: 14-Feb-2007

DATE RECEIVED IN LABORATORY: 15-Feb-2007

DATE REPORTED BY LABORATORY: 21-Feb-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S1008

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

sICAM-1

sICAM-1


319

H

115-306 ng/mL

[ ]

[✓]

  
Investigator Signature:2/23/07  
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

B17173

(INV)

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**LABORATORY REPORT**

ACCESSION NO. N526699

Page 1 of 1

INVESTIGATOR: (B17173)

Bryan Pogue, M.D.

c/o Sherepta Mcleod

6565 W Emerald St.

Boise, ID United States 83704

PROTOCOL 6270-229

INVESTIGATOR NO.: 1

RANDOMIZATION NUMBER: R1002

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

SPONSOR REPORT TO:

Russell M. Dixon, MD

Medical Director

Covance CRU, Inc.

3402 Kinsman Boulevard

Madison, WI United States 53704

COLLECTION TIME:06:58 DATE:14-Feb-2007

DATE RECEIVED IN LABORATORY: 15-Feb-2007

DATE REPORTED BY LABORATORY: 21-Feb-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S1008

Is this Clinically  
Significant/ Adverse  
Event?


Yes

No

RBC CELL WASHING (4-ABP-HB)

Wash/Store

Completed

  
Investigator Signature:2/23/07  
Date:

H(High) or L(Low)=Values above or below Covance CLS reference range  
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B17173

(INV)



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ACCESSION NO. N526699

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Boise, ID United States 83704

PROTOCOL 6270-229

INVESTIGATOR NO.: 1

RANDOMIZATION NUMBER: R1002

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

SPONSOR REPORT TO:

Russell M. Dixon, MD

Medical Director

Covance CRU, Inc.

3402 Kinsman Boulevard

Madison, WI United States 53704

COLLECTION TIME: 06:58 DATE: 14-Feb-2007

DATE RECEIVED IN LABORATORY: 15-Feb-2007

DATE REPORTED BY LABORATORY: 19-Apr-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S1008

Is this Clinically  
Significant/ Adverse  
Event?

Yes No

HOMOCYSTEINE

\*1 HCY

9.63

5.90-16.00 umol/L

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 ~~may have elevated levels of homocysteine due to their effect on the metabolic pathway~~

APR 20 2007

Investigator Signature:

Date:

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

B17173

(INV)



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**LABORATORY REPORT**

ACCESSION NO. N526699

Page 1 of 1

INVESTIGATOR: (B17173)

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6565 W Emerald St.

Boise, ID United States 83704

PROTOCOL 6270-229

INVESTIGATOR NO.: 1

RANDOMIZATION NUMBER: R1002

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

SPONSOR REPORT TO:

Russell M. Dixon, MD

Medical Director

Covance CRU, Inc.

3402 Kinsman Boulevard

Madison, WI United States 53704

COLLECTION TIME:06:58 DATE:14-Feb-2007

DATE RECEIVED IN LABORATORY: 15-Feb-2007

DATE REPORTED BY LABORATORY: 16-Feb-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S1008

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

HEMOGLOBIN A1C

Hgb A1c

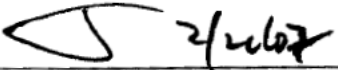
5.0

Normals:

4.3-6.1%

Stable Diabetics:

4.2-11.2%

  
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

B17173

(INV)

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**LABORATORY REPORT**

ACCESSION NO. N526699

Page 1 of 1

## INVESTIGATOR: (B17173)

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Boise, ID United States 83704

PROTOCOL 6270-229

INVESTIGATOR NO.: 1

RANDOMIZATION NUMBER: R1002

PATIENT INITIALS: (b) (6)

VISIT: 2

## SPONSOR REPORT TO:

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

Week 0

COLLECTION TIME:06:58 DATE:14-Feb-2007

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DATE REPORTED BY LABORATORY: 16-Feb-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S1008

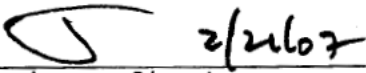
Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

## LIPID PANEL

Triglycer	89	50-321 mg/dL
Cholest	180	150-264 mg/dL
HDL Dex-S	42	29-62 mg/dL
LDL Chol	120	78-185 mg/dL

  
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

B17173

(INV)

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8211 SciCor Drive - Indianapolis, IN 46214-2985  
Tel. +1 (800) 327 7270

**LABORATORY REPORT**

ACCESSION NO. N526767

Page 1 of 1

INVESTIGATOR: (B17173)

Bryan Pogue, M.D.  
c/o Sherepta Mcleod  
6565 W Emerald St.  
Boise, ID United States 83704

PROTOCOL 6270-229

INVESTIGATOR NO.: 1

RANDOMIZATION NUMBER: R1002

PATIENT INITIALS: (b) (6)

VISIT: 4

SPONSOR REPORT TO:

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

Week 2

COLLECTION TIME: 12:25 DATE: 28-Feb-2007

DATE RECEIVED IN LABORATORY: 01-Mar-2007

DATE REPORTED BY LABORATORY: 01-Mar-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S1008

Is this Clinically  
Significant/ Adverse  
Event?

Yes

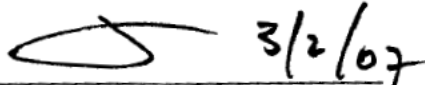
No

CARBOXYHEMOGLOBIN

Carboxyhem 5.5

% saturation

No Ref Rng

  
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

B17173

(INV)



10012848930001

**LABORATORY REPORT**

**REPORT OF DATA REVISIONS**

**INVESTIGATOR:**

Bryan Pogue, M.D.  
c/o Sherepta Mcleod  
6565 W Emerald St.  
Boise, ID United States 83704

**PROTOCOL:** 6270-229

**INVESTIGATOR NO.:** 1

**RANDOMIZATION NUMBER:** R1003

**PATIENT INITIALS:** (b) (6)

**SPONSOR REPORT TO:**

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

**DATE REVISED:** 21-Feb-2007

**DATE PRINTED:** 21-Feb-2007

**DATA ELEMENT:** Randomization Number  
**REVISED FROM:** R1009  
**REVISED TO:** R1003  
**AUTHORIZED BY:** Sherepta McLeod - Site

This revision has been made in the Covance CLS database.  
It applies to the following visit data previously reported:

Visit	Visit Description	Visit Date	Accession No.
1	Screen	31-Jan-2007	NS26639
2	Week 0	14-Feb-2007	NS26729

**RECEIVED**

MAR 02 2007

B17173

Study No. 207268 / Protocol No. 6270-229  
3/13/07 **Screening Lab Tests Results**  
Urine Drug Screen, Urine Dipstick, Urine Pregnancy Test, and Alcohol Breath Test

Document Version Date: 17-Jan-2007

Page 1 of 2

(b) (6) Screening # 1008 R1002  
Date of Test: 13 MAR 2007  
(dd/mm/yyyy)

Lot# 070704 Exp. Date: 2009-07-07  
Urine Dipstick - Adulta Check® 6 90°

Time of Urine Application (24 hour clock)	Oxidants Read between 15-30 seconds	Creatinine Read between 30-60 seconds	Nitrite Read immediately	Glutaraldehyde Read immediately	pH Read immediately	Chromate Read immediately	Staff Init
1156	Neg	20 Norm	Neg	Neg	5.0 Norm	Neg	LS

Lot# DoA608493 Exp. Date: 2008/08  
Urine Drug Screen - EZ Split Key™

Time of Key Insertion (24 hour clock)	Staff Init	AMP	COC	THC	mAMP	OPI	PCP	BZO	BAR	MTD	MDMA	Time Result Recorded (24 hour clock)	Staff Init
1157	LS	<input type="checkbox"/> pos <input checked="" type="checkbox"/> neg	<input type="checkbox"/> pos <input checked="" type="checkbox"/> neg	<input type="checkbox"/> pos <input checked="" type="checkbox"/> neg	<input type="checkbox"/> pos <input checked="" type="checkbox"/> neg	<input type="checkbox"/> pos <input checked="" type="checkbox"/> neg	<input type="checkbox"/> pos <input checked="" type="checkbox"/> neg	<input type="checkbox"/> pos <input checked="" type="checkbox"/> neg	<input type="checkbox"/> pos <input checked="" type="checkbox"/> neg	<input type="checkbox"/> pos <input checked="" type="checkbox"/> neg	<input type="checkbox"/> pos <input checked="" type="checkbox"/> neg	1202	LS

Study No. 207268 / Protocol No. 6270-229

Document Version Date: 17-Jan-2007

ET Screening Lab Tests Results

3/13/07

Breath Alcohol Test

Page 2 of 2

Time Test Performed (24 hour clock): \_\_\_\_\_:

Brand: Lisuloc Model or Lot#: \_\_\_\_\_ Exp. Date (if disposable test): \_\_\_\_\_

Calibration Cannister Brand(if using a digital device) and Exp date: \_\_\_\_\_

Test Results (from digital display)	Is Test Result Within Acceptable Range?	Time of results (24 hr. clock)	Staff Init
<u>0.000</u>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		<u>R</u>

Urine Pregnancy Test

Brand: \_\_\_\_\_ Lot# \_\_\_\_\_ Exp. Date: \_\_\_\_\_

male

Test Results	Time of Results (24 hour clock)	Staff Init
<input type="checkbox"/> positive <input type="checkbox"/> negative		

Bryan C. Pogue, M.D.

Investigator Results Review: \_\_\_\_\_  
Signature Date

APR 02 2007

Date \_\_\_\_\_



**Covance CLS**

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

**LABORATORY REPORT**

ACCESSION NO. N527977

Page 1 of 1

INVESTIGATOR: (B17173)

Bryan Pogue, M.D.  
c/o Sherepta Mcleod  
6565 W Emerald St.  
Boise, ID United States 83704

PROTOCOL 6270-229

INVESTIGATOR NO.: 1

RANDOMIZATION NUMBER: R1002

PATIENT INITIALS: (b) (6)

VISIT: 15

SPONSOR REPORT TO:

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

Week 24/Early Term

COLLECTION TIME: 11:30 DATE: 13-Mar-2007

DATE RECEIVED IN LABORATORY: 14-Mar-2007

DATE REPORTED BY LABORATORY: 15-Mar-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S1008

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

HOMOCYSTEINE

Homocys

7.73

5.90-16.00 umol/L

Bryan C. Pogue, M.D.

MAR 20 2007

Investigator Signature:

Date:

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

B17173

(INV)



**Covance CLS**

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**LABORATORY REPORT**

ACCESSION NO. N527977

Page 1 of 1

## INVESTIGATOR: (B17173)

Bryan Pogue, M.D.  
c/o Sherepta Mcleod  
6565 W Emerald St.  
Boise, ID United States 83704

PROTOCOL 6270-229

INVESTIGATOR NO.: 1

RANDOMIZATION NUMBER: R1002

PATIENT INITIALS: (b) (6)

VISIT: 15

## SPONSOR REPORT TO:

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

Week 24/Early Term

COLLECTION TIME: 11:30 DATE: 13-Mar-2007

DATE RECEIVED IN LABORATORY: 14-Mar-2007

DATE REPORTED BY LABORATORY: 15-Mar-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S1008

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

## FIBRINOGEN

Fibrinogen 256 200-400 mg/dL

Bryan C. Pogue, M.D.

MAR 20 2007

Investigator Signature:

Date:

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B17173

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Page 1 of 1

INVESTIGATOR: (B17173)

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6565 W Emerald St.  
Boise, ID United States 83704

PROTOCOL 6270-229

INVESTIGATOR NO.: 1

RANDOMIZATION NUMBER: R1002

PATIENT INITIALS: (b) (6)

VISIT: 15

Week 24/Early Term

SPONSOR REPORT TO:

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

COLLECTION TIME: 11:30 DATE: 13-Mar-2007

DATE RECEIVED IN LABORATORY: 14-Mar-2007

DATE REPORTED BY LABORATORY: 14-May-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S1008

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

OXIDIZED LDL - See Note #1

Note #1 - No specimen received

Investigator Signature:

Date:

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

B17173

(INV)

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PROTOCOL 6270-229

INVESTIGATOR NO.: 1

RANDOMIZATION NUMBER: R1002

PATIENT INITIALS: (b) (6)

VISIT: 15

SPONSOR REPORT TO:

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

Week 24/Early Term

COLLECTION TIME: 11:30 DATE: 13-Mar-2007

DATE RECEIVED IN LABORATORY: 14-Mar-2007

DATE REPORTED BY LABORATORY: 30-Mar-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S1008

Is this Clinically  
Significant/ Adverse  
Event?


Yes

No

sICAM-1

sICAM-1 310 H 115-306 ng/mL

[ ]

[ ☒ ]**Bryan C. Pogue, M.D.**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

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ACCESSION NO. N527977

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6565 W Emerald St.

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PROTOCOL 6270-229

INVESTIGATOR NO.: 1

RANDOMIZATION NUMBER: R1002

PATIENT INITIALS: (b) (6)

VISIT: 15

Week 24/Early Term

SPONSOR REPORT TO:

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Medical Director

Covance CRU, Inc.

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Madison, WI United States 53704

COLLECTION TIME: 11:30 DATE: 13-Mar-2007

DATE RECEIVED IN LABORATORY: 14-Mar-2007

DATE REPORTED BY LABORATORY: 19-Apr-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S1008

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

HOMOCYSTEINE

\*1 HCY

7.73

5.90-16.00 umol/L

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.

*Bryan C. Pogue, M.D.*

Investigator Signature:

APR 20 2007

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PROTOCOL 6270-229

INVESTIGATOR NO.: 1

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VISIT: 15

Week 24/Early Term

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SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S1008

Is this Clinically  
Significant/ Adverse  
Event?

Yes No

## TOTAL IRON

Total Iron 88 45-160 ug/dL

## C-REACTIVE PROTEIN

CRP-HS 0.038 <=0.287 mg/dL

## CARBOXYHEMOGLOBIN

Carboxyhem 4.2 % saturation  
No Ref Rng

*Bryan C. Pogue, M.D.*  
MAR 16 2007

Investigator Signature:

Date:

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

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(INV)

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**LABORATORY REPORT**

ACCESSION NO. N527977

Page 1 of 3

INVESTIGATOR: (B17173)

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PROTOCOL 6270-229

INVESTIGATOR NO.: 1

RANDOMIZATION NUMBER: R1002

PATIENT INITIALS: (b) (6)

VISIT: 15

Week 24/Early Term

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Madison, WI United States 53704

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DATE REPORTED BY LABORATORY: 14-Mar-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S1008

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

## CHEMISTRY PANEL

Total Bili	0.3	0.2-1.2 mg/dL
Alk Phos	73	31-129 U/L
ALT (SGPT)	15	6-43 U/L
AST (SGOT)	20	11-36 U/L
GGT	13	10-61 U/L
LDH	139	53-234 U/L
Urea Nitr	14	4-24 mg/dL
Creatinine	0.9	0.5-1.2 mg/dL
Glucose	104	70-115 mg/dL
Uric Acid	5.0	2.1-8.2 mg/dL
Calcium	9.8	8.3-10.6 mg/dL
Phosphorus	3.7	2.2-5.1 mg/dL
Total Prot	7.4	6.1-8.4 g/dL
Albumin	4.7	3.3-4.9 g/dL
Sodium	140	132-147 mEq/L
Potassium	4.3	3.4-5.4 mEq/L
Chloride	103	94-112 mEq/L

Bryan C. Pogue, M.D.

MAR 16 2007

Investigator Signature:

Date:

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

B17173

(INV)

**Covance CLS**

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

**LABORATORY REPORT**

ACCESSION NO. N527977

Page 2 of 3

**INVESTIGATOR: (B17173)**

Bryan Pogue, M.D.  
c/o Sherepta Mcleod  
6565 W Emerald St.  
Boise, ID United States 83704

PROTOCOL 6270-229

INVESTIGATOR NO.: 1

RANDOMIZATION NUMBER: R1002

PATIENT INITIALS: (b) (6)

VISIT: 15

Week 24/Early Term

**SPONSOR REPORT TO:**

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

COLLECTION TIME: 11:30 DATE: 13-Mar-2007

DATE RECEIVED IN LABORATORY: 14-Mar-2007

DATE REPORTED BY LABORATORY: 14-Mar-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S1008

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

**HEMATOLOGY& DIFFERENTIAL PANEL**

HGB	15.2	12.7-18.1 g/dL
HCT	45	39-54 %
RBC	5.0	4.5-6.4x10 <sup>6</sup> /uL
MCV	91	79-96 fL
MCH	30	26-34 pg
MCHC	34	31-38 g/dL
RDW	13.1	12.0-15.0 %
RBC Morph	Normocytic	
WBC	7.69	3.80-10.70 x10 <sup>3</sup> /uL
Neutrophil	5.10	1.96-7.23 x10 <sup>3</sup> /uL
Lymphocyte	2.09	0.91-4.28 x10 <sup>3</sup> /uL
Monocytes	0.39	0.12-0.92 x10 <sup>3</sup> /uL
Eosinophil	0.07	0.00-0.57 x10 <sup>3</sup> /uL
Basophils	0.04	0.00-0.20 x10 <sup>3</sup> /uL
Neutrophil	66.3	40.5-75.0 %
Lymphocyte	27.2	15.4-48.5 %
Monocytes	5.1	2.6-10.1 %
Eosinophil	0.9	0.0-6.8 %
Basophils	0.5	0.0-2.0 %
Platelets	203	140-400 x10 <sup>3</sup> /uL

Bryan C. Pogue, M.D.

MAR 16 2007

Investigator Signature:

Date:

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

B17173

(INV)



**Covance CLS**

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**LABORATORY REPORT**

ACCESSION NO. N527977

Page 3 of 3

## INVESTIGATOR: (B17173)

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PROTOCOL 6270-229

INVESTIGATOR NO.: 1

RANDOMIZATION NUMBER: R1002

PATIENT INITIALS: (b) (6)

VISIT: 15

Week 24/Early Term

## SPONSOR REPORT TO:

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

COLLECTION TIME: 11:30 DATE: 13-Mar-2007

DATE RECEIVED IN LABORATORY: 14-Mar-2007

DATE REPORTED BY LABORATORY: 14-Mar-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S1008

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

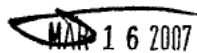
## URINE MACRO &amp; MICRO PANEL

Color	Yellow	Ref Rng: Colorless or Yellow
Clarity	Clear	Ref Rng: Clear
Spec Grav	1.016	1.003-1.035
pH	6.0	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
Nitrite	Negative	Ref Rng: Negative
Leuk Est	Negative	Ref Rng: Negative
Microscop	Positive	

## MISCELLANEOUS ELEMENTS

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

Bryan C. Pogue, M.D.

  
MAR 16 2007

Investigator Signature:

Date:

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

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(INV)



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PROTOCOL 6270-229

INVESTIGATOR NO.: 1

RANDOMIZATION NUMBER: R1002

PATIENT INITIALS: (b) (6)

VISIT: 15

Week 24/Early Term

SPONSOR REPORT TO:

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

COLLECTION TIME: 11:30 DATE: 13-Mar-2007

DATE RECEIVED IN LABORATORY: 14-Mar-2007

DATE REPORTED BY LABORATORY: 14-Mar-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S1008

Is this Clinically  
Significant/ Adverse  
Event?

Yes No

URINE CREATININE, SPOT

Rnd Ur Crt 85

mg/dL No Ref Rng

*Bryan C. Pogue, M.D.*

MAR 16 2007

Investigator Signature:

Date:

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PROTOCOL 6270-229

INVESTIGATOR NO.: 1

RANDOMIZATION NUMBER: R1002

PATIENT INITIALS: (b) (6)

VISIT: 15

Week 24/Early Term

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3402 Kinsman Boulevard  
Madison, WI United States 53704

COLLECTION TIME: 11:30 DATE: 13-Mar-2007

DATE RECEIVED IN LABORATORY: 14-Mar-2007

DATE REPORTED BY LABORATORY: 14-Mar-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S1008

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

RBC CELL WASHING (4-ABP-HB)

Wash/Store Completed

*Bryan C. Pogue, M.D.*

MAR 16 2007

Investigator Signature:

Date:

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ACCESSION NO. N527977

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PROTOCOL 6270-229

INVESTIGATOR NO.: 1

RANDOMIZATION NUMBER: R1002

PATIENT INITIALS: (b) (6)

VISIT: 15

Week 24/Early Term

SPONSOR REPORT TO:

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Medical Director  
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3402 Kinsman Boulevard  
Madison, WI United States 53704

COLLECTION TIME: 11:30 DATE: 13-Mar-2007

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DATE REPORTED BY LABORATORY: 14-Mar-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S1008

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

HEMOGLOBIN A1C

Hgb A1c

5.2

Normals:

4.3-6.1%

Stable Diabetics:

4.2-11.2%

*Bryan C. Pogue, M.D.*

MAR 16 2007

Investigator Signature:

Date:

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(INV)

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**LABORATORY REPORT**

ACCESSION NO. N527977

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## INVESTIGATOR: (B17173)

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6565 W Emerald St.  
Boise, ID United States 83704

PROTOCOL 6270-229

INVESTIGATOR NO.: 1

RANDOMIZATION NUMBER: R1002

PATIENT INITIALS: (b) (6)

VISIT: 15

## SPONSOR REPORT TO:

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

Week 24/Early Term

COLLECTION TIME: 11:30 DATE: 13-Mar-2007

DATE RECEIVED IN LABORATORY: 14-Mar-2007

DATE REPORTED BY LABORATORY: 14-Mar-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S1008

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

HAS PATIENT FASTED 8 HOURS?

Fasted? Yes

Bryan C. Pogue, M.D.

MAR 16 2007

Investigator Signature:

Date:

B17173

(INV)

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**LABORATORY REPORT**

ACCESSION NO. N527977

Page 1 of 1

INVESTIGATOR: (B17173)

Bryan Pogue, M.D.

c/o Sherepta Mcleod

6565 W Emerald St.

Boise, ID United States 83704

PROTOCOL 6270-229

INVESTIGATOR NO.: 1

RANDOMIZATION NUMBER: R1002

PATIENT INITIALS: (b) (6)

VISIT: 15

Week 24/Early Term

SPONSOR REPORT TO:

Russell M. Dixon, MD

Medical Director

Covance CRU, Inc.

3402 Kinsman Boulevard

Madison, WI United States 53704

COLLECTION TIME: 11:30 DATE: 13-Mar-2007

DATE RECEIVED IN LABORATORY: 14-Mar-2007

DATE REPORTED BY LABORATORY: 14-Mar-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S1008

Is this Clinically  
Significant/ Adverse  
Event?

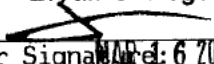
Yes

No

LIPID PANEL - See Note #1

Note #1 - No specimen received

Bryan C. Pogue, M.D.

Investigator Signature:  MAR 16 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

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(INV)

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**LABORATORY REPORT**

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INVESTIGATOR: (B17173)

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6565 W Emerald St.

Boise, ID United States 83704

PROTOCOL 6270-229

INVESTIGATOR NO.: 1

RANDOMIZATION NUMBER: R1002

PATIENT INITIALS: (b) (6)

VISIT: 15

Week 24/Early Term

SPONSOR REPORT TO:

Russell M. Dixon, MD

Medical Director

Covance CRU, Inc.

3402 Kinsman Boulevard

Madison, WI United States 53704

COLLECTION TIME: 11:30 DATE: 13-Mar-2007

DATE RECEIVED IN LABORATORY: 14-Mar-2007

DATE REPORTED BY LABORATORY: 14-Mar-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S1008

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:

Bryan C. Pogue, M.D.

MAR 16 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

B17173

(INV)

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

ACCESSION NO. N527977

Page 1 of 1

**INVESTIGATOR: (B17173)**

Bryan Pogue, M.D.  
c/o Sherepta Mcleod  
6565 W Emerald St.  
Boise, ID United States 83704

PROTOCOL 6270-229

INVESTIGATOR NO.: 1

RANDOMIZATION NUMBER: R1002

PATIENT INITIALS: (b) (6)

VISIT: 15

**SPONSOR REPORT TO:**

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

Week 24/Early Term

COLLECTION TIME: 11:30 DATE: 13-Mar-2007

DATE RECEIVED IN LABORATORY: 14-Mar-2007

DATE REPORTED BY LABORATORY: 14-Mar-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S1008

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

FIBRINOGEN - See Note #1

Fibrinogen Awaiting specimen arrival

*Bryan C. Pogue, M.D.*

MAR 16 2007

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

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

B17173

(INV)

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Tel. +1 (800) 327 7270

**LABORATORY REPORT**

ACCESSION NO. N527977

Page 1 of 1

INVESTIGATOR: (B17173)

Bryan Pogue, M.D.

c/o Sherepta Mcleod

6565 W Emerald St.

Boise, ID United States 83704

PROTOCOL 6270-229

INVESTIGATOR NO.: 1

RANDOMIZATION NUMBER: R1002

PATIENT INITIALS: (b) (6)

VISIT: 15

Week 24/Early Term

SPONSOR REPORT TO:

Russell M. Dixon, MD

Medical Director

Covance CRU, Inc.

3402 Kinsman Boulevard

Madison, WI United States 53704

COLLECTION TIME: 11:30 DATE: 13-Mar-2007

DATE RECEIVED IN LABORATORY: 14-Mar-2007

DATE REPORTED BY LABORATORY: 14-Mar-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S1008

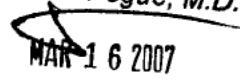
Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

OXIDIZED LDL - See Note #1

OxidizeLDL Awaiting specimen arrival

Bryan C. Pogue, M.D.  


MAR 16 2007

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

Investigator Signature:

Date:

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

Testing performed by: Pacific Biometrics

220 West Harrison Street; Seattle, WA 98119

B17173

(INV)



**Covance CLS**

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

**LABORATORY REPORT**

ACCESSION NO. N526699

Page 1 of 1

## INVESTIGATOR: (B17173)

Bryan Pogue, M.D.  
c/o Sherepta McLeod  
Covance CRU  
6565 W Emerald St.  
Boise, ID 83704

## 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.: 1

RANDOMIZATION NUMBER: R1002

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 06:58 DATE: 14-Feb-2007

DATE RECEIVED IN LABORATORY: 15-Feb-2007

DATE REPORTED BY LABORATORY: 21-Jan-2008

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S1008

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

OXIDIZED LDL

OxidizeLDL

82

30-110 U/L

*Bryan C. Pogue, M.D.*

JAN 30 2008

Investigator Signature:

Date:

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

B17173

(187)

**Covance CLS**

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

**LABORATORY REPORT**

ACCESSION NO. N527948

Page 1 of 1

## INVESTIGATOR: (B17173)

Bryan Pogue, M.D.  
c/o Sherepta McLeod  
Covance CRU, Inc-Boise  
6565 W Emerald St.  
Boise, ID 83704

## 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.: 1

RANDOMIZATION NUMBER: R1002

PATIENT INITIALS: (b) (6)

VISIT: 24 HR UR

24 Hr Urine Collection

COLLECTION TIME:14:55 DATE:13-Feb-2007

DATE RECEIVED IN LABORATORY: 16-Feb-2007

DATE REPORTED BY LABORATORY: 02-Feb-2008

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S1008

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

## TOTAL 24-HR URINE VOLUME

Total Vol. 1810 mL

 06 Feb 2008

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

B17173

(INV)

**Covance CLS**

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

ACCESSION NO. N527948

Page 1 of 1

## INVESTIGATOR: (B17173)

Bryan Pogue, M.D.  
c/o Sherepta McLeod  
Covance CRU, Inc-Boise  
6565 W Emerald St.  
Boise, ID 83704

## 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.: 1

RANDOMIZATION NUMBER: R1002

PATIENT INITIALS: (b) (6)

VISIT: 24 HR UR

24 Hr Urine Collection

COLLECTION TIME: 14:55 DATE: 13-Feb-2007

DATE RECEIVED IN LABORATORY: 16-Feb-2007

DATE REPORTED BY LABORATORY: 03-Feb-2008

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S1008

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

## 24 HR COLLECTION INFORMATION

Start Date 13-Feb-2007  
Start Time 14:55  
Stop Date 14-Feb-2007  
Stop Time 15:09

Investigator Signature:

Date:

H(High) or L(Low)=Values above or below Covance CLS reference range  
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B17173

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## INVESTIGATOR: (B17173)

Bryan Pogue, M.D.  
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Covance CRU, Inc-Boise  
6565 W Emerald St.  
Boise, ID 83704

## 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.: 1

RANDOMIZATION NUMBER: R1002

PATIENT INITIALS: (b) (6)

VISIT: 24 HR UR

24 Hr Urine Collection

COLLECTION TIME: 14:55 DATE: 13-Feb-2007

DATE RECEIVED IN LABORATORY: 16-Feb-2007

DATE REPORTED BY LABORATORY: 01-Feb-2008

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S1008

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

ELAPSED DATE AND TIME, 24HR

Elpsd D&amp;T 1454 min

Investigator Signature:

Date:

H(High) or L(Low)=Values above or below Covance CLS reference range  
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B17173

(INV)

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**INVESTIGATOR: (B17173)**

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Boise, ID 83704

**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.: 1

RANDOMIZATION NUMBER: R1002

PATIENT INITIALS: (b) (6)

VISIT: 24 HR UR

24 Hr Urine Collection

COLLECTION TIME: 14:55 DATE: 13-Feb-2007

DATE RECEIVED IN LABORATORY: 16-Feb-2007

DATE REPORTED BY LABORATORY: 04-Feb-2008

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S1008

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

**URINE CREATININE, 24 HR**

U24h Creat 1377

UAlq24Crea 76.8

800-1800 mg/24hr

mg/dL No Ref Rng

**ELAPSED DATE AND TIME, 24HR**

Elpsd D&amp;T 1454

min

**24 HR COLLECTION INFORMATION**

Start Date 13-Feb-2007

Start Time 14:55

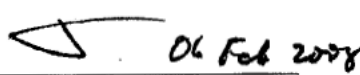
Stop Date 14-Feb-2007

Stop Time 15:09

**TOTAL 24HR URINE VOLUME**

Total Vol. 1810

mL

  
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

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(INV)