

# CRF Report for Study E6270229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Header\_Page

Blank? N

CRF Page #: 1

Visit: SCREENING

Visit Date: 26-03-2007

Document #: R139576013

Entered By: Ben Heven

Entry Time: 26-04-2007 11:40:16

CRF Status: Entry Complete

Discrepancies: None

Modification Time: 26-04-2007 11:41:18

Approval Status: Not Approved

Approval Time:

Approver:

Verification: Not Verified

Verification Time:

Verifier:

Comment:

Section: Header\_Info

Blank? N

Section Status: Entry Complete

Visit: SCREENING

Section Date: 26-03-2007

Entered By: Ben Heven

Entry Time: 26-04-2007 11:40:16

Last Modification Time: 26-04-2007 11:41:18

Page number: 1

RDC CASE REPORT FORM

SMOKER

Sponsor Name

Investigator

Site

RJ REYNOLDS TOBACCO COMPANY

DAVID CARTER

CA\_001

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

age ID: D11548813

/ Covance No. 6270-229

Data Clarification Form

o:Covance CRU Austin  
Investigator:David Carter  
ate:25-FEB-2008

Patient#:5004  
Patient Initials:  
Reviewer:Dawn Taylor

orm Name / Visit Name	Page # Date	Questions/Comments	Resolution
Medical History SCREENING Disc ID: 1317906313 Type: MANUAL	3 26MAR07 Closed: N	'Date of Resolution/Ongoing is not provided for finding 'Tubal Ligation'.	<input checked="" type="checkbox"/> Date of resolution=16-09-1998 <input type="checkbox"/> Other:_____

22  
3MAR08

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.

Auranele Lynn  
Authorized Personnel Signature

26 Feb-2008  
Date

age ID: D11445713

/ Covance No. 6270-229

Data Clarification Form

o:Covance CRU Austin  
Investigator:David Carter  
ate:06-FEB-2008

Patient#:5004  
Patient Initials:  
Reviewer:Dawn Taylor

orm Name / Visit Name	Page # Date	Questions/Comments	Resolution
Physical Exam WEEK 12 Disc ID: 1304044113 Type: MANUAL	15 09JUL07 Closed: N	Relevant Findings for 'Other' is indicated as 'NO'. Please clarify response.	<input checked="" type="checkbox"/> Change response to 'Not Examined'. <input type="checkbox"/> Other (specify)

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.

Amanda Lynn  
Authorized Personnel Signature

08-Feb-2008  
Date

age ID: D11302313

/ Covance No. 6270-229

Data Clarification Form

o:Covance CRU Austin  
Investigator:David Carter  
ate:28-JAN-2008

Patient#:5004  
Patient Initials:  
Reviewer:Dawn Taylor

Form Name / Visit Name	Page # Date	Questions/Comments	Resolution
Laboratory Evaluation WEEK 0 (BASELINE) Disc ID: 1294312313 Type: MANUAL HEADER	5 15APR07 Closed: N	On the W0 24 hour sICAM-1 lab requisition (#0062482) the Randomization Number and Screening Number appear to be switched. Please correct and forward updated lab documents with this dcf.	<input checked="" type="checkbox"/> Lab paperwork updated. Req attached. [ ] Other: _____
Medical History SCREENING Disc ID: 1292718613 Type: MANUAL	3 26MAR07 Closed: N	For consistency of reporting this finding, and more appropriately presenting associated 'System', please verify that 'Tubal Ligation' should be presented at System 'Genitourinary'.	<input checked="" type="checkbox"/> Tubal Ligation System=Genitourinary [ ] Other: _____

① lab is not attached - expecting later delivery 01/20/2008  
② request as resolution is not provided for finding 01/20/2008

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

Amanah Lyne  
Authorized Personnel Signature

29/Jan/2008  
Date



**Covance CLS**

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

**LABORATORY REPORT**

\*\*\*\* REPRINTED: 4-Mar-08 \*\*\*\*

ACCESSION NO. 0062482

Page 1 of 1

**INVESTIGATOR: (B17181)**

David Carter, M.D.  
 c/o Marianna Alesi  
 Covance-Austin  
 313 East Anderson Lane #200  
 Austin, TX 78752

PROTOCOL 6270-229

INVESTIGATOR NO.: 5

RANDOMIZATION NUMBER: R5004

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: 15:29 DATE: 15-Apr-2007

DATE RECEIVED IN LABORATORY: 17-Apr-2007

DATE REPORTED BY LABORATORY: 03-Mar-2008

SEX: F BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5018

Is this Clinically  
 Significant/ Adverse  
 Event?

Yes

No

**CHEMISTRY PANEL**

Total Bili	0.2		0.2-1.2 mg/dL
Alk Phos	114	H	31-106 U/L
ALT (SGPT)	14		6-34 U/L
AST (SGOT)	18		9-34 U/L
GGT	36		4-49 U/L
LDH	132		53-234 U/L
Urea Nitr	14		4-24 mg/dL
Creatinine	0.9		0.4-1.1 mg/dL
Glucose	96		70-115 mg/dL
Uric Acid	3.9		2.1-7.2 mg/dL
Calcium	9.8		8.3-10.6 mg/dL
Phosphorus	4.0		2.2-5.1 mg/dL
Total Prot	7.4		6.1-8.4 g/dL
Albumin	4.1		3.3-4.9 g/dL
Sodium	141		132-147 mEq/L
Potassium	4.2		3.4-5.4 mEq/L
Chloride	105		94-112 mEq/L

[ ]

[X]

Investigator Signature:

15 MAR 2008

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

B17181

(INV)

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c/o Marianna Alesi  
Covance-Austin  
313 East Anderson Lane #200  
Austin, TX 78752

**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.: 5  
RANDOMIZATION NUMBER: R5004  
PATIENT INITIALS: (b) (6)  
VISIT: 2

Week 0

COLLECTION TIME: 15:29 DATE: 15-Apr-2007  
DATE RECEIVED IN LABORATORY: 17-Apr-2007  
DATE REPORTED BY LABORATORY: 03-Mar-2008  
SEX: F BIRTHDATE: (b) (6) AGE: 36  
SCREENING NUMBER: S5018


Is this Clinically  
Significant/ Adverse  
Event?

Yes

☒ No**CARBOXYHEMOGLOBIN**

Carboxyhem 9.6

% saturation  
No Ref Rng

  
Investigator Signature:

15 May 2008  
Date:

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Austin, TX 78752

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.: 5

RANDOMIZATION NUMBER: R5004

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

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SCREENING NUMBER: S5018

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

HOMOCYSTEINE

\*1 HCY 8.35 3.36-20.44 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.

Investigator Signature:

Date:

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PROTOCOL 6270-229

INVESTIGATOR NO.: 5

RANDOMIZATION NUMBER: R5004

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: 15:29 DATE: 15-Apr-2007

DATE RECEIVED IN LABORATORY: 16-Apr-2007

DATE REPORTED BY LABORATORY: 03-Mar-2008

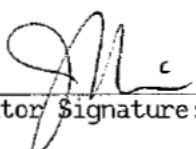
SEX: F BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5018

Is this Clinically  
Significant/ Adverse  
Event?  
Yes ☐ No ☒

**FIBRINOGEN**

Fibrinogen 257 200-400 mg/dL

  
Investigator Signature:

15 MAR 2008  
Date:

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3402 Kinsman Boulevard  
Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 5

RANDOMIZATION NUMBER: R5004

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 15:29 DATE: 15-Apr-2007

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SEX: F BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5018

Is this Clinically  
Significant/ Adverse  
Event?


Yes

No

URINE CREATININE, SPOT

Rnd Ur Crt 66

mg/dL No Ref Rng

  
Investigator Signature:

  
Date:

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B17181

(INV)

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Austin, TX 78752

PROTOCOL 6270-229

INVESTIGATOR NO.: 5

RANDOMIZATION NUMBER: R5004

PATIENT INITIALS: (b) (6)

VISIT: 2

**SPONSOR REPORT TO:**

Russell M. Dixon, MD  
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Madison, WI United States 53704

Week 0

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DATE REPORTED BY LABORATORY: 03-Mar-2008

SEX: F BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5018

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

sICAM-1

sICAM-1

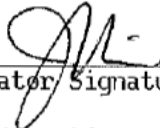
494

H

115-306 ng/mL

[ ]

[ ]

  
Investigator Signature:

15 MAR 2008  
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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Page 1 of 1

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Covance-Austin  
313 East Anderson Lane #200  
Austin, TX 78752

PROTOCOL 6270-229

INVESTIGATOR NO.: 5

RANDOMIZATION NUMBER: R5004

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: 15:29 DATE: 15-Apr-2007

DATE RECEIVED IN LABORATORY: 16-Apr-2007

DATE REPORTED BY LABORATORY: 03-Mar-2008

SEX: F BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5018

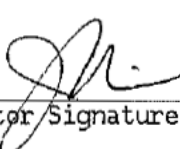
Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

RBC CELL WASHING (4-ABP-HB)

Wash/Store Completed

  
Investigator Signature:

15mar2008  
Date:

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B17181

(INV)

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

**LABORATORY REPORT**

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ACCESSION NO. 0062482

Page 1 of 1

**INVESTIGATOR: (B17181)**

David Carter, M.D.  
c/o Marianna Alesi  
Covance-Austin  
313 East Anderson Lane #200  
Austin, TX 78752

PROTOCOL 6270-229  
INVESTIGATOR NO.: 5  
RANDOMIZATION NUMBER: R5004  
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

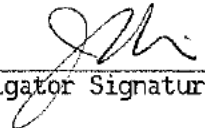
COLLECTION TIME: 15:29 DATE: 15-Apr-2007  
DATE RECEIVED IN LABORATORY: 16-Apr-2007  
DATE REPORTED BY LABORATORY: 03-Mar-2008  
SEX: F BIRTHDATE: (b) (6) AGE: 36  
SCREENING NUMBER: S5018

Is this Clinically  
Significant/ Adverse  
Event?

Yes No

**HAS PATIENT FASTED 8 HOURS?**

Fasted? Yes

  
Investigator Signature:

15 Mar 2008  
Date:

B17181

(INV)



**Covance CLS**

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

**LABORATORY REPORT**

\*\*\*\* REPRINTED: 4-Mar-08 \*\*\*\*

ACCESSION NO. 0062482

Page 1 of 1

INVESTIGATOR: (B17181)

David Carter, M.D.

c/o Marianna Alesi

Covance-Austin

313 East Anderson Lane #200

Austin, TX 78752

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.: 5

RANDOMIZATION NUMBER: R5004

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 15:29 DATE: 15-Apr-2007

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SEX: F BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5018

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

HEMOGLOBIN A1C

Hgb A1c


5.6

Normals:

4.3-6.1%

Stable Diabetics:

4.2-11.2%

  
Investigator Signature:

15MAR2008  
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

B17181

(INV)

**Covance CLS**

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

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Medical Director  
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3402 Kinsman Boulevard  
Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 5

RANDOMIZATION NUMBER: R5004

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

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SEX: F BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5018


Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

**LIPID PANEL**

Triglycer	137	39-176 mg/dL
Cholest	190	141-240 mg/dL
HDL Dex-S	35	34-82 mg/dL
LDL Chol	128	75-172 mg/dL

  
Investigator Signature:

15 MAR 2008  
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

B17181

(INV)

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PROTOCOL 6270-229

INVESTIGATOR NO.: 5

RANDOMIZATION NUMBER: R5004

PATIENT INITIALS: (b) (6)

VISIT: 2

**SPONSOR REPORT TO:**

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3402 Kinsman Boulevard  
Madison, WI United States 53704

Week 0

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SEX: F BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5018

Is this Clinically  
Significant/ Adverse  
Event?

Yes

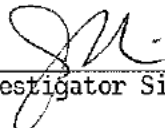
No

**OXIDIZED LDL**

OxidizeLDL

99

30-110 U/L

  
Investigator Signature:

15 MAR 2008  
Date:

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

B17181

(INV)

age ID: D11302213

/ Covance No. 6270-229

Data Clarification Form

o: Covance CRU Austin  
Investigator: David Carter  
ate: 28-JAN-2008

Patient#: 5004  
Patient Initials:  
Reviewer: Dawn Taylor

Form Name / Visit Name	Page # Date	Questions/Comments	Resolution
4-Hour Urine Collection WEEK 0 (BASELINE) Disc ID: 1292730813 Type: MANUAL HEADER	5 15APR07 Closed: N	On the W0 24 hour urine collect lab requisition (#N528366) the Randomization Number and Screening Number appear to be switched. Please correct and forward updated lab documents with this dcf.	<input checked="" type="checkbox"/> Lab paperwork updated. Req attached. <input type="checkbox"/> Other: _____
4-Hour Urine Collection WEEK 12 Disc ID: 1292956713 Type: MANUAL	15 09JUL07 Closed: N	1-W12 0-24H Urine Collection notes a volume of 1150.5. Lab documents note a volume of 1151. Please verify the volume, to a whole number.  2-W12 0-24H Urine Collection notes a start time of 14:57. Lab documents note a start time of 14:58. Please verify start time.  3-Please verify the Time for the W12 Spot Urine Void.	1- <input type="checkbox"/> 1150 Updated lab req attached <input checked="" type="checkbox"/> 1151  2- <input checked="" type="checkbox"/> 14:57 Updated lab req attached <input type="checkbox"/> 14:58  3- <input checked="" type="checkbox"/> 14:57 <input type="checkbox"/> 14:58

*① req not attached - expecting later delivery Dm2 021008*

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.

*Amanda Lynn*  
Authorized Personnel Signature

*29/Jan/2008*  
Date



10013349490001

**LABORATORY REPORT**

**REPORT OF DATA REVISIONS**

**INVESTIGATOR:**

David Carter, M.D.  
c/o Marianna Alesi  
Covance-Austin  
313 East Anderson Lane #200  
Austin, TX 78752

**PROTOCOL:** 6270-229

**INVESTIGATOR NO.:** 5

**RANDOMIZATION NUMBER:** R5004

**PATIENT INITIALS:** (b)

**SPONSOR REPORT TO:**

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

**DATE REVISED:** 05-Feb-2008

**DATA ELEMENT:** Start Time  
**REVISED FROM:** 14:58  
**REVISED TO:** 14:57  
**AUTHORIZED BY:** Mary Alesi - Site

**DATA ELEMENT:** Elpsd D&T  
**REVISED FROM:** 1440  
**REVISED TO:** 1441  
**REFERENCE RANGE:** min  
**AUTHORIZED BY:** Mary Alesi - Site

**DATA ELEMENT:** U24h Creat  
**REVISED FROM:** 956  
**REVISED TO:** 955  
**REFERENCE RANGE:** 600-1600 mg/24hr  
**AUTHORIZED BY:** Mary Alesi - 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.
24 HR UR	24 Hr Urine Collection	09-Jul-2007	P150649

JA  
15MAR2008

B17181

**Covance CLS**

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

**LABORATORY REPORT**

ACCESSION NO. P150649

Page 1 of 1

**INVESTIGATOR: (B17181)**

David Carter, M.D.  
c/o Marianna Alesi  
Covance-Austin  
313 East Anderson Lane #200  
Austin, TX 78752

**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.:** 5**RANDOMIZATION NUMBER:** R5004**PATIENT INITIALS:** (b) (6)**VISIT:** 24 HR UR

24 Hr Urine Collection


**COLLECTION TIME:** 14:58 **DATE:** 09-Jul-2007**DATE RECEIVED IN LABORATORY:** 11-Jul-2007**DATE REPORTED BY LABORATORY:** 07-Feb-2008**SEX:** F **BIRTHDATE:** (b) (6) **AGE:** 36**SCREENING NUMBER:** S5018

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

**24 HR COLLECTION INFORMATION****Start Date** 09-Jul-2007**Start Time** 14:57**Stop Date** 10-Jul-2007**Stop Time** 14:58

  
Investigator Signature:

19 Feb 2008  
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

B17181

(INV)

age ID: D11302413

/ Covance No. 6270-229

Data Clarification Form

o:Covance CRU Austin  
Investigator:David Carter  
ate:28-JAN-2008

Patient#:5004  
Patient Initials:  
Reviewer:Dawn Taylor

orm Name / Visit Name	Page # Date	Questions/Comments	Resolution
Pregnancy Test WEEK 0 (BASELINE) Disc ID: 1292726313 Type: MANUAL	5 15APR07 Closed: N	This subject is Female, however the W0 Pregnancy Test date=ND, result=N/A.	<div><div><input type="checkbox"/> Date=15-04-2007 Result=Negative</div><div><input checked="" type="checkbox"/> Date=15-04-2007 Result= <u>ND</u> - inadvertently was not done have a note to file for this</div><div><input checked="" type="checkbox"/> Date= _____ Result= _____</div></div> <div>AL</div>
Pregnancy Test WEEK 12 Disc ID: 1292941713 Type: MANUAL	15 09JUL07 Closed: N	This subject is Female, however the W12 Pregnancy Test result=N/A.	<div><div><input checked="" type="checkbox"/> Result=Negative</div><div><input type="checkbox"/> Result= _____</div></div> <div>AL</div>

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.

Amanela Lynn  
Authorized Personnel Signature

29/Jan/2008  
Date

age ID: D11302613

/ Covance No. 6270-229

Data Clarification Form

o:Covance CRU Austin  
Investigator:David Carter  
ate:28-JAN-2008

Patient#:5004  
Patient Initials:  
Reviewer:Dawn Taylor

orm Name / Visit Name	Page # Date	Questions/Comments	Resolution
Usual Brand Cigarette Butt Collection WEEK 0 (BASELINE Disc ID: 1292741913 Type: MANUAL	5.1 16APR07 Closed: N	W0 'Number of Usual Brand Cigarette Butts Collected' provided is '30', however only 20 measurements are provided.	<input checked="" type="checkbox"/> Number of Butts Collected=20  <input type="checkbox"/> Butt # 21, _____mm Butt # 22, _____mm Butt # 23, _____mm Butt # 24, _____mm Butt # 25, _____mm Butt # 26, _____mm Butt # 27, _____mm Butt # 28, _____mm Butt # 29, _____mm Butt # 30, _____mm

W0m2  
02-10-08

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.

Amanda Lynn  
Authorized Personnel Signature

29/Jan/2008  
Date



age ID: D11302513

/ Covance No. 6270-229

Data Clarification Form

o:Covance CRU Austin  
Investigator:David Carter  
ate:28-JAN-2008

Patient#:5004  
Patient Initials:  
Reviewer:Dawn Taylor

orm Name / Visit Name	Page # Date	Questions/Comments	Resolution
Used Study Snus Collection VEEK 12 Disc ID: 1292966213 Type: MANUAL	16 09JUL07 Closed: N	Response to the W12 'Usual Brand Cigarette Butt Collection' Any Product Deviation? Question is 'No', however response is provided for 'If yes, number of butts other than usual brand' is provided.	<input checked="" type="checkbox"/> Delete 'N/A' <input type="checkbox"/> Other:_____
Used Study Tobacco-Burning Cigarette Butt Measurement VEEK 12 Disc ID: 1292974013 Type: MANUAL HEADER	09JUL07 Closed: N	As this subject was randomized to SNUS, please confirm that the W12 'Usual Study Tobacco-Burning Cigarette Butt Measurement' & 'Used Study Tobacco- Burning Cigarette Butt Measurement' modules are to be marked as 'Blank'.	<input checked="" type="checkbox"/> Update modules Blank?=Y <input type="checkbox"/> Other:_____

ama  
02/16/08

ama  
02/16/08

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.

Amanda Lynn  
Authorized Personnel Signature

29/Jan/2008  
Date

# CRF Report for Study E6270229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Screening

Blank? N

CRF Page #: 2

Visit: SCREENING

Visit Date: 26-03-2007

Document #: R139576613

Entered By: Ben Heven

Entry Time: 26-04-2007 11:41:19

CRF Status: Entry Complete

Discrepancies: None

Modification Time: 19-11-2007 10:29:21

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: 26-03-2007

Entered By: Ben Heven

Entry Time: 26-04-2007 11:41:19

Last Modification Time: 13-06-2007 05:05:32

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: 26-03-2007

Entered By: Ben Heven

Entry Time: 26-04-2007 11:41:19

Last Modification Time: 26-04-2007 12:24:43

Page number: 20

## INCLUSION CRITERIA

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

# CRF Report for Study Eb270229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Screening

Blank? N

CRF Page #: 2

Visit: SCREENING

Visit Date: 26-03-2007

Document #: R139576613

Section: Inc\_Criteria 2 of 10

11	at Screening; and for all females of child-bearing potential, the pregnancy test results must be negative at Weeks 0, 12, and 24), non-lactating, and either postmenopausal (as verified by FSH levels) for at least 1 year, surgically sterile ( e.g. tubal ligation, hysterectomy, etc.) for at least 90 days, or agree to use from the time of signing the informed consent until 30 days after Week 24 (of Study Completion) a form of contraception considered acceptable to the Investigators (such as oral, injectable, or implantable contraceptives, intrauterine devices and barrier methods).	YES
12	Able to comprehend and willing to sign an Informed Consent Form (ICF).	YES
13	Able to read and comprehend questionnaires in English.	YES

Section: Exc\_Criteria 3 of 10

Blank? N

Section Status: Entry Complete

Visit: SCREENING

Section Date: 26-03-2007

Entered By: Ben Heyen

Entry Time: 26-04-2007 11:41:19

Last Modification Time: 26-04-2007 12:24:43

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 Investigator(s)' opinion, is clinically significant.	NO
05	History of alcoholism or drug addiction within 1 year prior to Study Entry; excessive alcohol consumption will be discouraged.	NO
06	Poor peripheral venous access.	NO
07	Donation of blood from 30 days prior to Screening through Week 24 (or Study Completion), inclusive, or of plasma from 2 weeks prior to Screening through Week 24 (or Study Completion), inclusive.	NO
08	Receipt of blood products within 2 months prior to Study Entry.	NO
09	Evidence of visible oral cancer, as found in an oral health examination or based on oral health questions at each visit.	NO
10	Any acute or chronic condition that, in the Investigator(s)' opinion, would limit the subject's ability to complete and/or participate in this clinical study.	NO
11	Subject or a relative of the subject is or has ever been employed by the tobacco industry.	NO
12	Subject is an employee of Covance.	NO
13	Subject has participated in any other investigational study drug or product trial in which receipt of an investigational study drug or product occurred within 30 days prior to Check-in (inclusive).	NO

# CRF Report for Study E6270229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Screening

Blank? N

CRF Page #: 2

Visit: SCREENING

Visit Date: 26-03-2007

Document #: R139576613

Section: Informed Consent 4 of 10

Blank? N

Section Status: Entry Complete

Visit: SCREENING

Section Date: 26-03-2007

Entered By: Ben Heyen

Entry Time: 26-04-2007 11:41:19

Last Modification Time: 26-04-2007 12:24:43

Page number: 4

## Informed Consent

Date the Subject Signed the Smoker Informed Consent Form

26-03-2007

Section: Elig 5 of 10

Blank? N

Section Status: Entry Complete

Visit: SCREENING

Section Date: 26-03-2007

Entered By: Ben Heyen

Entry Time: 26-04-2007 11:41:19

Last Modification Time: 26-04-2007 12:24:43

Page number: 4

## Subject Eligibility

Did the subject meet all of the inclusion criteria?

YES

Did the subject have any of the exclusion criteria?

NO

Criteria Type	Criteria Number	Deviation	Date Exemption	Granted

Section: Patient\_Rep\_Outc 6 of 10

Blank? N

Section Status: Entry Complete

Visit: SCREENING

Section Date: 26-03-2007

Entered By: Ben Heyen

Entry Time: 26-04-2007 11:41:19

Last Modification Time: 26-04-2007 12:24:43

Page number: 4

## Patient Reported Outcome (PRO) Questionnaires

Did the subject complete the Smoker Screening Questionnaire prior to any study procedures being performed?

Yes / No

YES

Section: Demog 7 of 10

Blank? N

Section Status: Entry Complete

Visit: SCREENING

Section Date: 26-03-2007

Entered By: Ben Heyen

Entry Time: 26-04-2007 11:41:19

Last Modification Time: 26-04-2007 12:24:43

Page number: 5

## Demographics

## Subject Initials

(b)

Date of Birth	Gender	Height	Height Unit	Weight	Weight Unit
(b) (6)	F	153.6	CM	049.1	KG
		xxx.x		xxx.x	

## Ethnicity

# CRF Report for Study E6270229

Patient: 5004

CRF: Screening

Visit: SCREENING

Site: CA\_001

Blank? N

Visit Date: 26-03-2007

Investigator: C2785\_03

CRF Page #: 2

Document #: R139576613

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: 26-03-2007

Entered By: Ben Heyen

Entry Time: 26-04-2007 11:41:19

Last Modification Time: 26-04-2007 12:24:43

Page number: 5

## VITAL SIGNS

Actual Time	Blood Pressure		Pulse	Respiratory Rate	Oral	Unit
	Systolic	Diastolic			Temperature	
1111	103	69	63	18	36.5	C
					xxx.x	

Comments

Section: Hdvf\_Oral\_Health 9 of 10

Blank? N

Section Status: Entry Complete

Visit: SCREENING

Section Date: 26-03-2007

Entered By: Ben Heyen

Entry Time: 26-04-2007 11:41:19

Last Modification Time: 26-04-2007 12:24:43

Page number: 5

## HDYF? / ORAL HEALTH QUESTIONS INQUIRY

Actual Time	HDYF Performed?	Oral Health	Comments
		Questions Performed?	
1047	YES	YES	

Section: Lab\_Eval 10 of 10

Blank? N

Section Status: Entry Complete

Visit: SCREENING

Section Date: 26-03-2007

Entered By: Ben Heyen

Entry Time: 26-04-2007 11:41:19

Last Modification Time: 18-09-2007 15:28:29

Page number: 6

## Laboratory Evaluations

Were the scheduled laboratory samples obtained? YES No, specify

Requisition Number 1 O062460

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 E6210229

Patient: 5004

Site: CA\_001

CRF: Screening

Blank? N

Visit: SCREENING

Visit Date: 26-03-2007

Investigator: C2785\_03

CRF Page #: 2

Document #: R139576613

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

# CRF Report for Study E6270229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Screening2

Blank? N

CRF Page #: 3

Visit: SCREENING

Visit Date: 26-03-2007

Document #: R139713013

Entered By: Ben Heyen

Entry Time: 27-04-2007 10:01:39

CRF Status: Entry Complete

Discrepancies: Closed

Modification Time: 30-11-2007 13:27:47

Approver:

Approval Status: Not Approved

Approval Time:

Verifier:

Verification: Not Verified

Verification Time:

Comment:

Section: Preg_Test	1 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 26-03-2007	
Entered By: Ben Heyen		Entry Time: 27-04-2007 10:01:39	
		Last Modification Time: 27-04-2007 10:13:09	
		Page number: 6	

Urine Pregnancy Test  
Result  
NEGATIVE

Section: Urine_Drug	2 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 26-03-2007	
Entered By: Ben Heyen		Entry Time: 27-04-2007 10:01:39	
		Last Modification Time: 27-04-2007 10:13:09	
		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: 26-03-2007	
Entered By: Ben Heyen		Entry Time: 27-04-2007 10:01:39	
		Last Modification Time: 27-04-2007 10:13:09	
		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: 26-03-2007	
Entered By: Ben Heyen		Entry Time: 27-04-2007 10:01:39	
		Last Modification Time: 29-11-2007 21:54:14	
		Page number: 7	

# CRF Report for Study EbZ10229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Screening2

Blank? N

CRF Page #: 3

Visit: SCREENING

Visit Date: 26-03-2007

Document #: R139713013

Section: Med\_Hx

4 of 10

## Medical History

Does the subject have any relevant medical history?

YES

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

System	Diagnosis/Procedure	Date of Onset	Date of Resolution/Ongoing
SKIN			
EENT			
BREASTS			
RESP			
CARDIO			
LYMPH/HEMA			
GASTRO			
GENITO			
MUSCULO			
ENDOCRINE			
NEURO			
IMMUNO			
PSYCH			
ALLERGIC			
OTHER	TUBAL LIGATION	16-09-1998	

Section: ECG

5 of 10

Blank? N

Section Status: Entry Complete

Visit: SCREENING

Section Date: 26-03-2007

Entered By: Ben Heyen

Entry Time: 27-04-2007 10:01:39

Last Modification Time: 27-04-2007 10:13:09

Page number: 8

## 12-LEAD ELECTROCARDIOGRAM REPORT

Actual Time

Ventricular Heart Rate

1118

66

### Cardiac Cycle Measurements

PR Interval

QRS Duration

QT Interval

QTc Interval

176

102

392

402

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: 26-03-2007

Entered By: Ben Heyen

Entry Time: 27-04-2007 10:01:39

Last Modification Time: 29-11-2007 21:51:46



# CRF Report for Study Eb270229

Patient: 5004  
CRF: Screening2  
Visit: SCREENING

Site: CA\_001  
Blank? N  
Visit Date: 26-03-2007

Investigator: C2785\_03  
CRF Page #: 3  
Document #: R139713013

Section: Usual\_Brand\_Cig 6 of 10

Page number: 9

USUAL BRAND CIGARETTE PACK		DATA
Usual Brand	Type	Length
MARLBORO	NON-MENTHOL	KING SIZE 83-85MM
Style	Pack	How long have these been the subject's usual brand?
MILD/MEDIUMS	HARD	6 months
		10 years

Section: Ftc\_Tar\_Level

7 of 10

Blank? N

Section Status: Entry Complete

Visit: SCREENING

Section Date: 26-03-2007

Entered By: Ben Heven

Entry Time: 27-04-2007 10:01:39

Last Modification Time: 18-09-2007 15:32:49

Page number: 9

## FTC TAR LEVEL OF USUAL BRAND

FTC Tar Level (mg)  
11.3

Section: Expired\_Carbon\_M

8 of 10

Blank? N

Section Status: Entry Complete

Visit: SCREENING

Section Date: 26-03-2007

Entered By: Ben Heven

Entry Time: 27-04-2007 10:01:39

Last Modification Time: 14-11-2007 16:34:47

Page number: 10

## EXPIRED CARBON MONOXIDE

Actual Time	ECO Level (ppm)	%COHb	Comments
1056	17	3.3	

Section: Best\_Baseline\_Sp

9 of 10

Blank? N

Section Status: Entry Complete

Visit: SCREENING

Section Date: 26-03-2007

Entered By: Ben Heven

Entry Time: 27-04-2007 10:01:39

Last Modification Time: 18-09-2007 15:45:05

Page number: 10

## BEST BASELINE SPIROMETRY TEST RESULT

Actual Time of FEV1/FVC Test	Testing Position	FEV1 L	FEV 1 Predicted (%)	FVC L	FVC Predicted (%)	Comments
1050	STANDING	2.41	84	3.25	94	

Irvs Training

10 10

N

Entry Complete

# CRF Report for Study Eb270229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Screening2

Blank? N

CRF Page #: 3

Visit: SCREENING

Visit Date: 26-03-2007

Document #: R139713013

Section: Irvs\_Training

10 of 10

Blank?

Section Status:

Visit: SCREENING

Section Date: 26-03-2007

Entered By: Ben Heyen

Entry Time: 27-04-2007 10:01:39

Last Modification Time: 27-04-2007 10:13:09

Page number: 10

## IVRS TRAINING

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

YES

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

# CRF Report for Study Eb210229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Week-2

Blank? N

CRF Page #: 4

Visit: WEEK -2

Visit Date: 30-03-2007

Document #: R139716813

Entered By: Ben Heyen

Entry Time: 27-04-2007 10:13:31

CRF Status: Entry Complete

Discrepancies: None

Modification Time: 27-04-2007 10:14:19

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: 30-03-2007

Entered By: Ben Heyen

Entry Time: 27-04-2007 10:13:31

Last Modification Time: 27-04-2007 10:14:19

Page number: 11

## USUAL BRAND

## CIGARETTE COLLECTION TRAINING

1. Did subject receive foam block?

YES

2. Did subject receive training on usual brand collection?

YES

3. Was subject provided usual brand cigarettes for Week 0  
cigarette butt collection?

YES

# CRF Report for Study EbZ10229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Week 0 Baseline

Blank? N

CRF Page #: 5

Visit: WEEK 0 (BASELINE)

Visit Date: 15-04-2007

Document #: R145054313

Entered By: Ben Heyen

Entry Time: 13-06-2007 06:40:57

CRF Status: Entry Complete

Discrepancies: Closed

Modification Time: 29-11-2007 21:57:53

Approval Status: Not Approved

Approval Time:

Approver:

Verification: Not Verified

Verification Time:

Verifier:

Comment:

Section: Pro\_Questionnair

1 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 15-04-2007

Entered By: Ben Heyen

Entry Time: 13-06-2007 06:40:57

Last Modification Time: 13-06-2007 06:48:06

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
15-04-2007		YES

Section: Urine\_Drug

2 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 15-04-2007

Entered By: Ben Heyen

Entry Time: 13-06-2007 06:40:57

Last Modification Time: 13-06-2007 06:48:06

Page number: 12A

## Drug Screen

Date	Drug Screen Result
15-04-2007	NEG

Section: Alcohol\_Screen

3 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 15-04-2007

Entered By: Ben Heyen

Entry Time: 13-06-2007 06:40:57

Last Modification Time: 29-11-2007 21:46:03

Page number: 12A

## Alcohol Screen

Date	Breathalyzer Result
15-04-2007	ND

Section: Preg\_Test

4 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 15-04-2007

Entered By: Ben Heyen

Entry Time: 13-06-2007 06:40:57

Last Modification Time: 14-11-2007 16:37:08

Page number: 12A

# CRF Report for Study E6270229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Week 0 Baseline

Blank? N

CRF Page #: 5

Visit: WEEK 0 (BASELINE)

Visit Date: 15-04-2007

Document #: R145054313

Section: Preg\_Test 4 of 11

## Pregnancy Test

Date	Result
ND	N/A, MALE OR FEMA LE

Section: Urine\_Coll 5 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 15-04-2007

Entered By: Ben Heven

Entry Time: 13-06-2007 06:40:57

Last Modification Time: 14-11-2007 16:37:46

Page number: 12A

## 24-Hour Urine Collection

Scheduled Timepoint	Start Date	Start Time	Stop Date	Stop Time	Total Volume	Comments
SPOT URINE VOID	15-04-2007	1529	NA	NA	NA	
0 HOUR TO 24 HOURS	15-04-2007	1529	16-04-2007	1523	660	

Section: Hdyl\_Oral\_Health 6 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 15-04-2007

Entered By: Ben Heven

Entry Time: 13-06-2007 06:40:57

Last Modification Time: 14-11-2007 15:48:35

Page number: 13.1

## HDYF? INQUIRY

Date	Actual Time	HDYF Performed?	Comments
16-04-2007	0646	YES	

Section: Vital 7 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 15-04-2007

Entered By: Ben Heven

Entry Time: 13-06-2007 06:40:57

Last Modification Time: 13-06-2007 06:48:06

Page number: 13.1

## VITAL SIGNS

Date	Actual Time	Blood Pressure		Pulse	Respiratory Rate	Oral	Unit
		Systolic	Diastolic			Temperature	
15-04-2007	1518	107	73	85	13	ND	NA

# CRF Report for Study E6270229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Week 0 Baseline

Blank? N

CRF Page #: 5

Visit: WEEK 0 (BASELINE)

Visit Date: 15-04-2007

Document #: R145054313

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: 15-04-2007

Entered By: Ben Heven

Entry Time: 13-06-2007 06:40:57

Last Modification Time: 29-11-2007 21:57:53

Page number: 13.1

## ORAL HEALTH EXAMINATION

Date

15-04-2007

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: 15-04-2007

Entered By: Ben Heven

Entry Time: 13-06-2007 06:40:57

Last Modification Time: 13-06-2007 06:48:06

Page number: 14.1

## PHYSICAL EXAMINATION

Date

15-04-2007

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

Section: Weight\_Height 10 of 11

Blank? N

Section Status: Entry Complete

# CRF Report for Study E6270229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Week 0 Baseline

Blank? N

CRF Page #: 5

Visit: WEEK 0 (BASELINE)

Visit Date: 15-04-2007

Document #: R145054313

Section: Weight\_Height 10 of 11

Visit: WEEK 0 (BASELINE)

Entered By: Ben Heyen

Section Date: 15-04-2007

Entry Time: 13-06-2007 06:40:57

Last Modification Time: 18-09-2007 15:52:44

Page number: 14.1

## WEIGHT & HEIGHT

Date	Weight	Unit	Height	Unit
15-04-2007	49.6	KG	NA	
	xxx.x		xxx.x	

Section: Lab\_Eval 11 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Entered By: Ben Heyen

Section Date: 15-04-2007

Entry Time: 13-06-2007 06:40:57

Last Modification Time: 18-09-2007 15:54:51

Page number: 15.1

## Laboratory Evaluations

Date

15-04-2007

Were the scheduled laboratory samples obtained?

YES

No, specify

Requisition Number 1

O062482

Requisition Number 2 (if applicable)

N528366

Were there any clinically significant labs?

NO

(Yes, specify below)

Requisition Number

Test Name

H/L

Lab ID

Lab Name

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

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

# CRF Report for Study Eb270229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Week 0 2baseline

Blank? N

CRF Page #: 5.1

Visit: WEEK 0 (BASELINE)

Visit Date: 16-04-2007

Document #: R145085313

Entered By: Ben Heyen

Entry Time: 13-06-2007 10:26:13

CRF Status: Entry Complete

Discrepancies: None

Modification Time: 26-09-2007 11:49:52

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: 16-04-2007

Entered By: Ben Heyen

Entry Time: 13-06-2007 10:26:13

Last Modification Time: 13-06-2007 10:42:02

Page number: 15.1

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

Date	Actual Time	Comments
16-04-2007	0715	

Section: Expired\_Carbon\_M 2 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 13-06-2007 10:26:13

Last Modification Time: 13-06-2007 10:42:02

Page number: 15.1

EXPIRED CARBON MONOXIDE

Date	Actual Time	ECO Level (ppm)	%COHb	Comments
16-04-2007	1559	34	06.0	

Section: Blood\_Sampl\_Cohb 3 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 13-06-2007 10:26:13

Last Modification Time: 13-06-2007 10:42:02

Page number: 15.1

Blood Sampling for %COHb

Date	Actual Time	Comments
16-04-2007	1601	

Section: Pre\_Bronch\_Spir 4 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 13-06-2007 10:26:13

Last Modification Time: 13-06-2007 10:42:02

Page number: 16.1



# CRF Report for Study E6270229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Week 0 2baseline

Blank? N

CRF Page #: 5.1

Visit: WEEK 0 (BASELINE)

Visit Date: 16-04-2007

Document #: R145085313

Section: Pre\_Bronch\_Splr 4 of 11

## PRE-BRONCHODILATOR BEST BASELINE SPIROMETRY TEST RESULT

Actual Time  
of FEV1/FVC

Date	Test	Testing Position	FEV1 L	FEV1 Predicted (%)	FVC L	FVC Predicted (%)	Comments
16-04-2007	1631	STANDI NG	2.57	89	3.95	114	

Section: Proventil\_Admin 5 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 13-06-2007 10:26:13

Last Modification Time: 13-06-2007 10:42:02

Page number: 16.1

## PROVENTIL ADMINISTRATION

Actual Time  
of Proventil  
Administration

Date	Amount Administered	Comments
16-04-2007	1643	2 METERED PUFFS

Section: Post\_Bronch\_Splr 6 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 13-06-2007 10:26:13

Last Modification Time: 13-06-2007 10:42:02

Page number: 16.1

## POST-BRONCHODILATOR BEST SPIROMETRY TEST RESULT

Actual Time  
of FEV1/FVC

Date	Test	Testing Position	FEV1 L	FEV1 Predicted (%)	FVC L	FVC Predicted (%)	Comments
16-04-2007	1709	STANDING	2.43	84	2.61	75	

Section: Unused\_Usual\_Bra 7 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 13-06-2007 10:26:13

Last Modification Time: 13-06-2007 10:42:02

Page number: 17.1

## Unused Usual Brand Cigarette Pack Collection

Yes / No

Date	Does Site have 5 unopened packs of subject's usual brand cigarette to ship to CCLS?
16-04-2007	YES

YES

# CRF Report for Study Eb270229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Week 0 2baseline

Blank? N

CRF Page #: 5.1

Visit: WEEK 0 (BASELINE)

Visit Date: 16-04-2007

Document #: R145085313

Section: Usual\_Brand\_Butt

8 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 13-06-2007 10:26:13

Last Modification Time: 13-06-2007 10:42:02

Page number: 17.1

## Usual Brand Cigarette Butt Collection

Scheduled Collection	Start Date	Start Time	Stop Date	Stop Time	Number of Usual Brand Cigarette Butts Collected	Any Product Deviation?	If yes, number of butts other than usual brand:	Comments
24 HOURS PRIOR TO CHECK-IN	14-04- 2007	1530	15-04-2007	1530	21	NO		
24 HOURS IN-HOUSE	15-04- 2007	1530	16-04-2007	1530	30	NO		

Section: Used\_Butt\_Measur

9 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 13-06-2007 10:26:13

Last Modification Time: 18-09-2007 16:05:39

Page number: 18.1

## USUAL BRAND CIGARETTE BUTT MEASUREMENT

### Scheduled Collection

Date  
14-04-2007

Period  
24 HOURS PRIOR TO CHECK-IN

### Cigarette Butt Number

### Cigarette Butt Measurement (mm)

1	44
2	43
3	25
4	34
5	32
6	33
7	27
8	44
9	32
10	29
11	30
12	28
13	32
14	36
15	33
16	33
17	34

# CRF Report for Study Eb270229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Week 0 2baseline

Blank? N

CRF Page #: 5.1

Visit: WEEK 0 (BASELINE)

Visit Date: 16-04-2007

Document #: R145085313

Section: Used\_Butt\_Measur 9 of 11

18	32
19	31
20	40
21	31

Section: Used\_Butt\_Measur 10 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 13-06-2007 10:26:13

Last Modification Time: 18-09-2007 17:31:43

Page number: 19.1

## USUAL BRAND CIGARETTE BUTT MEASUREMENT

Scheduled Collection

Date  
15-04-2007

Period  
24 HOURS IN-HOUSE

Cigarette Butt Number

Cigarette Butt Measurement (mm)

1	35
2	33
3	28
4	29
5	30
6	29
7	32
8	28
9	27
10	28
11	27
12	32
13	27
14	31
15	30
16	26
17	30
18	28
19	29
20	30

Section: Randomization 11 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 13-06-2007 10:26:13

13-06-2007 10:42:02

# CRF Report for Study E6270229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Week 0 2baseline

Blank? N

CRF Page #: 5.1

Visit: WEEK 0 (BASELINE)

Visit Date: 16-04-2007

Document #: R145085313

Section: Randomization

11 of 11

Last Modification Time:

Page number: 20.1

	DATE	RANDOMIZATION	
	Date	Actual Time	Randomization Sequence
	16-04-2007	1737	GROUP B

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

# CRF Report for Study E6270229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Week 0 3baseline

Blank? N

CRF Page #: 5.2

Visit: WEEK 0 (BASELINE)

Visit Date: 16-04-2007

Document #: R145088513

Entered By: Ben Heyen

Entry Time: 13-06-2007 10:42:04

CRF Status: Entry Complete

Discrepancies: None

Modification Time: 18-12-2007 19:12:54

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: 16-04-2007

Entered By: Ben Heyen

Entry Time: 13-06-2007 10:42:04

Last Modification Time: 18-12-2007 19:12:54

Page number: 23.1

## STUDY PRODUCT DISPENSATION

Date	Actual Time	Product Dispensed	Flavor	Amount Dispensed
16-04-2007	1800	SNUS	FROST	1
16-04-2007	1800	SNUS	ORIGINAL	1
16-04-2007	1800	SNUS	SPICE	1

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

# CRF Report for Study E6270229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Intercurrent\_III

Blank? N

CRF Page #: 7

Visit: INTERCURRENT ILL

Visit Date: 16-04-2007

Document #: R166562313

Entered By: Ben Heyen

Entry Time: 14-11-2007 16:38:29

CRF Status: Entry Complete

Discrepancies: None

Modification Time: 14-11-2007 16:39:06

Approver:

Approval Status: Not Approved

Approval Time:

Verifier:

Verification: Not Verified

Verification Time:

Comment:

Section: Ip Findings

Blank? N

Section Status: Entry Complete

Visit: INTERCURRENT ILL

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 14-11-2007 16:38:29

Last Modification Time: 14-11-2007 16:39:06

Page number: 21

## Intercurrent Illness/Physical Findings

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

NO

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

# CRF Report for Study E6270229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Week 1

Blank? N

CRF Page #: 8

Visit: WEEK 1

Visit Date: 23-04-2007

Document #: R145055913

Entered By: Ben Heven

Entry Time: 13-06-2007 06:50:43

CRF Status: Entry Complete

Discrepancies: Active

Modification Time: 18-12-2007 19:18:44

Approver:

Approval Status: Not Approved

Approval Time:

Verifier:

Verification: Not Verified

Verification Time:

Comment:

Section: Hdyf_Oral_Health	1 of 5	Blank? N	Section Status: Entry Complete
Visit: WEEK 1		Section Date: 23-04-2007	
Entered By: Ben Heven		Entry Time: 13-06-2007 06:50:43	
		Last Modification Time: 21-09-2007 12:54:52	
		Page number: 22	

## HDYF? / ORAL HEALTH QUESTIONS INQUIRY

		Oral Health Questions Performed?	
Actual Time	HDYF Performed?		Comments
0809	YES	ND	

Section: Vital	2 of 5	Blank? N	Section Status: Entry Complete
Visit: WEEK 1		Section Date: 23-04-2007	
Entered By: Ben Heven		Entry Time: 13-06-2007 06:50:43	
		Last Modification Time: 13-06-2007 06:54:34	
		Page number: 22	

## VITAL SIGNS

	Blood Pressure				Oral	
Actual Time	Systolic	Diastolic	Pulse	Respiratory Rate	Temperature	Unit
0815	107	75	85	18	36.2	C
					xxx.x	

Comments

Section: Expired_Carbon_M	3 of 5	Blank? N	Section Status: Entry Complete
Visit: WEEK 1		Section Date: 23-04-2007	
Entered By: Ben Heven		Entry Time: 13-06-2007 06:50:43	
		Last Modification Time: 13-06-2007 06:54:34	
		Page number: 22	

## EXPIRED CARBON MONOXIDE

Actual Time	ECO Level (ppm)	%COHb	Comments
0819	12	02.5	

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

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Week 1

Blank? N

CRF Page #: 8

Visit: WEEK 1

Visit Date: 23-04-2007

Document #: R145055913

Section: Unused\_Study\_Pro 4 of 5

Visit: WEEK 1

Entered By: Ben Heyen

Section Date: 23-04-2007

Entry Time: 13-06-2007 06:50:43

Last Modification Time: 14-11-2007 16:09:37

Page number: 23

## Unused Study Product Returned

Product Returned	Flavor	Amount Returned	
		Packs	Individual Cigarettes / pouches
ND	NA	NA	NA

Section: Study\_Prod\_Dispe 5 of 5

Blank? N

Section Status: Entry Complete

Visit: WEEK 1

Entered By: Ben Heyen

Section Date: 23-04-2007

Entry Time: 13-06-2007 06:50:43

Last Modification Time: 18-12-2007 19:18:44

Page number: 23

## STUDY PRODUCT DISPENSATION

Actual Time	Product Dispensed	Flavor	Amount Dispensed
0825	SNUS	FROST	2

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

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



# CRF Report for Study E6270229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Week 2

Blank? N

CRF Page #: 9

Visit: WEEK 2

Visit Date: 30-04-2007

Document #: R145056613

Entered By: Ben Heyen

Entry Time: 13-06-2007 06:55:30

CRF Status: Entry Complete

Discrepancies: Active

Modification Time: 27-11-2007 23:24:15

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: 30-04-2007

Entered By: Ben Heyen

Entry Time: 13-06-2007 06:55:30

Last Modification Time: 14-11-2007 16:23:33

Page number: 24

## HDYF? / ORAL HEALTH QUESTIONS INQUIRY

Actual Time	HDYF Performed?	Oral Health Questions Performed?	Comments
0839	YES	ND	

Section: Vital

2 of 6

Blank? N

Section Status: Entry Complete

Visit: WEEK 2

Section Date: 30-04-2007

Entered By: Ben Heyen

Entry Time: 13-06-2007 06:55:30

Last Modification Time: 13-06-2007 06:57:04

Page number: 24

## VITAL SIGNS

Actual Time	Blood Pressure	Pulse	Respiratory Rate	Oral Temperature	Unit
0845	Systolic 85 Diastolic 59	69	12	37.1 xxx.x	C

Comments

Section: Expired\_Carbon\_M

3 of 6

Blank? N

Section Status: Entry Complete

Visit: WEEK 2

Section Date: 30-04-2007

Entered By: Ben Heyen

Entry Time: 13-06-2007 06:55:30

Last Modification Time: 13-06-2007 06:57:04

Page number: 24

## EXPIRED CARBON MONOXIDE

Actual Time	ECO Level (ppm)	%COHb	Comments
0901	6	01.5	

Section: Blood\_Sampl\_Cohb

4 of 6

Blank? N

Section Status: Entry Complete

# CRF Report for Study E6210229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Week 2

Blank? N

CRF Page #: 9

Visit: WEEK 2

Visit Date: 30-04-2007

Document #: R145056613

Section: Blood\_Sampl\_Cohb 4 of 6

Visit: WEEK 2

Entered By: Ben Heyen

Section Date: 30-04-2007

Entry Time: 13-06-2007 06:55:30

Last Modification Time: 13-06-2007 06:57:04

Page number: 24

Blood Sampling for %COHb

Actual Time

Comments

0903

Section: Unused\_Study\_Pro 5 of 6

Blank? N

Section Status: Entry Complete

Visit: WEEK 2

Entered By: Ben Heyen

Section Date: 30-04-2007

Entry Time: 13-06-2007 06:55:30

Last Modification Time: 27-11-2007 21:52:09

Page number: 25

Unused Study Product Returned

Amount Returned

Product Returned

Flavor

Packs

Individual Cigarettes / pouches

ND

ND

ND

ND

Section: Study\_Prod\_Dispe 6 of 6

Blank? N

Section Status: Entry Complete

Visit: WEEK 2

Entered By: Ben Heyen

Section Date: 30-04-2007

Entry Time: 13-06-2007 06:55:30

Last Modification Time: 14-11-2007 18:15:33

Page number: 25

STUDY PRODUCT DISPENSATION

Actual Time

Product Dispensed

Flavor

Amount Dispensed

0904

SNUS

FROST

3

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

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

# CRF Report for Study Eb210229

Patient: 5004	Site: CA_001	Investigator: C2785_03
CRF: Week 4	Blank? N	CRF Page #: 10
Visit: WEEK 4	Visit Date: 14-05-2007	Document #: R145056813
Entered By: Ben Heven	Entry Time: 13-06-2007 06:57:08	CRF Status: Entry Complete
Discrepancies: Active	Modification Time: 28-11-2007 09:58:20	
Approval Status: Not Approved	Approval Time:	Approver:
Verification: Not Verified	Verification Time:	Verifier:
Comment:		

Section: Pro_Questionnair	1 of 6	Blank? N	Section Status: Entry Complete
Visit: WEEK 4		Section Date: 14-05-2007	
Entered By: Ben Heven		Entry Time: 13-06-2007 06:57:08	
		Last Modification Time: 13-06-2007 06:57:46	
		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
		YES

Section: Hdyl_Oral_Health	2 of 6	Blank? N	Section Status: Entry Complete
Visit: WEEK 4		Section Date: 14-05-2007	
Entered By: Ben Heven		Entry Time: 13-06-2007 06:57:08	
		Last Modification Time: 14-11-2007 16:32:17	
		Page number: 26	

HDYF? / ORAL HEALTH QUESTIONS INQUIRY			
		Oral Health Questions	
Actual Time	HDYF Performed?	Performed?	Comments
0821	YES	ND	

Section: Vital	3 of 6	Blank? N	Section Status: Entry Complete
Visit: WEEK 4		Section Date: 14-05-2007	
Entered By: Ben Heven		Entry Time: 13-06-2007 06:57:08	
		Last Modification Time: 13-06-2007 06:57:46	
		Page number: 26	

VITAL SIGNS						
	Blood Pressure				Oral	
Actual Time	Systolic	Diastolic	Pulse	Respiratory Rate	Temperature	Unit
0830	99	70	69	16	36.2	C
					xxx.x	
Comments						

# CRF Report for Study E6270229

Patient: 5004

CRF: Week 4

Visit: WEEK 4

Site: CA\_001

Blank? N

Visit Date: 14-05-2007

Investigator: C2785\_03

CRF Page #: 10

Document #: R145056813

Section: Expired\_Carbon\_M 4 of 6

Blank? N

Section Status: Entry Complete

Visit: WEEK 4

Section Date: 14-05-2007

Entered By: Ben Heyen

Entry Time: 13-06-2007 06:57:08

Last Modification Time: 13-06-2007 06:58:52

Page number: 26

## EXPIRED CARBON MONOXIDE

Actual Time

ECO Level (ppm)

%COHb

Comments

0823

14

02.8

Section: Unused\_Study\_Pro 5 of 6

Blank? N

Section Status: Entry Complete

Visit: WEEK 4

Section Date: 14-05-2007

Entered By: Ben Heyen

Entry Time: 13-06-2007 06:57:08

Last Modification Time: 14-11-2007 16:30:18

Page number: 27

## Unused Study Product Returned

Product Returned

Flavor

Amount Returned

Packs

Individual Cigarettes / pouches

ND

NA

NA

NA

Section: Study\_Prod\_Dispe 6 of 6

Blank? N

Section Status: Entry Complete

Visit: WEEK 4

Section Date: 14-05-2007

Entered By: Ben Heyen

Entry Time: 13-06-2007 06:57:08

Last Modification Time: 14-11-2007 18:15:59

Page number: 27

## STUDY PRODUCT DISPENSATION

Actual Time

Product Dispensed

Flavor

Amount Dispensed

0903

SNUS

FROST

2

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

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

# CRF Report for Study E6210229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Week 6

Blank? N

CRF Page #: 11

Visit: WEEK 6

Visit Date: 30-05-2007

Document #: R158468313

Entered By: Cindy Prakop

Entry Time: 25-09-2007 10:33:39

CRF Status: Entry Complete

Discrepancies: Active

Modification Time: 28-11-2007 09:58:20

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 6

Section Date: 30-05-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 10:33:39

Last Modification Time: 27-11-2007 23:25:29

Page number: 28

## HDYF? / ORAL HEALTH QUESTIONS INQUIRY

Actual Time	HDYF Performed?	Oral Health Questions Performed?	Comments
1309	YES	ND	

Section: Expired\_Carbon\_M

2 of 5

Blank? N

Section Status: Entry Complete

Visit: WEEK 6

Section Date: 30-05-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 10:33:39

Last Modification Time: 25-09-2007 10:43:11

Page number: 28

## EXPIRED CARBON MONOXIDE

Actual Time	ECO Level (ppm)	%COHb	Comments
1318	30	05.4	

Section: Vital

3 of 5

Blank? N

Section Status: Entry Complete

Visit: WEEK 6

Section Date: 30-05-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 10:33:39

Last Modification Time: 25-09-2007 10:43:11

Page number: 28

## VITAL SIGNS

Actual Time	Blood Pressure		Pulse	Respiratory Rate	Oral	Unit
	Systolic	Diastolic			Temperature	
1315	118	085	087	16	036.9	C
					xxx.x	

Comments

Section: Unused\_Study\_Pro

4 of 5

Blank? N

Section Status: Entry Complete

# CRF Report for Study E6270229

Patient: 5004

CRF: Week 6

Visit: WEEK 6

Site: CA\_001

Blank? N

Visit Date: 30-05-2007

Investigator: C2785\_03

CRF Page #: 11

Document #: R158468313

Section: Unused\_Study\_Pro 4 of 5

Visit: WEEK 6

Entered By: Cindy Prakop

Section Date: 30-05-2007

Entry Time: 25-09-2007 10:33:39

Last Modification Time: 27-11-2007 23:25:52

Page number: 29

## Unused Study Product Returned

Product Returned	Flavor	Packs	Individual Cigarettes / pouches
ND	ND	ND	ND

Section: Study\_Prod\_Dispe 5 of 5

Visit: WEEK 6

Entered By: Cindy Prakop

Blank? N

Section Date: 30-05-2007

Entry Time: 25-09-2007 10:33:39

Last Modification Time: 25-09-2007 10:43:11

Page number: 29

Section Status: Entry Complete

## STUDY PRODUCT DISPENSATION

Actual Time	Product Dispensed	Flavor	Amount Dispensed
1324	SNUS	FROST	2

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

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

# CRF Report for Study E6270229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Week 8

Blank? N

CRF Page #: 13

Visit: WEEK 8

Visit Date: 11-06-2007

Document #: R158477213

Entered By: Cindy Prakop

Entry Time: 25-09-2007 10:46:51

CRF Status: Entry Complete

Discrepancies: Active

Modification Time: 28-11-2007 09:58:20

Approval Status: Not Approved

Approval Time:

Approver:

Verification: Not Verified

Verification Time:

Verifier:

Comment:

Section: Pro\_Questionnaire

1 of 6

Blank? N

Section Status: Entry Complete

Visit: WEEK 8

Section Date: 11-06-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 10:46:51

Last Modification Time: 25-09-2007 10:48:29

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

YES

Section: HDYF\_Oral\_Health

2 of 6

Blank? N

Section Status: Entry Complete

Visit: WEEK 8

Section Date: 11-06-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 10:46:51

Last Modification Time: 27-11-2007 23:26:06

Page number: 30

## HDYF? / ORAL HEALTH QUESTIONS INQUIRY

Actual Time	HDYF Performed?	Oral Health Questions Performed?	Comments
0910	YES	ND	

Section: Vital

3 of 6

Blank? N

Section Status: Entry Complete

Visit: WEEK 8

Section Date: 11-06-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 10:46:51

Last Modification Time: 25-09-2007 10:48:29

Page number: 30

## VITAL SIGNS

Actual Time	Blood Pressure		Pulse	Respiratory Rate	Oral	Unit
	Systolic	Diastolic			Temperature	
0920	098	069	069	14	036.3 xxx.x	C

Comments

# CRF Report for Study E6270229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Week 8

Blank? N

CRF Page #: 13

Visit: WEEK 8

Visit Date: 11-06-2007

Document #: R158477213

Section: Expired\_Carbon\_M

4 of 6

Blank? N

Section Status: Entry Complete

Visit: WEEK 8

Section Date: 11-06-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 10:46:51

Last Modification Time: 25-09-2007 10:48:29

Page number: 30

## EXPIRED CARBON MONOXIDE

Actual Time

ECO Level (ppm)

%COHb

Comments

0922

8

01.9

Section: Unused\_Study\_Pro

5 of 6

Blank? N

Section Status: Entry Complete

Visit: WEEK 8

Section Date: 11-06-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 10:46:51

Last Modification Time: 27-11-2007 23:26:25

Page number: 31

## Unused Study Product Returned

Product Returned

Flavor

Amount Returned

Packs

Individual Cigarettes / pouches

ND

ND

ND

ND

Section: Study\_Prod\_Dispe

6 of 6

Blank? N

Section Status: Entry Complete

Visit: WEEK 8

Section Date: 11-06-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 10:46:51

Last Modification Time: 25-09-2007 10:48:29

Page number: 31

## STUDY PRODUCT DISPENSATION

Actual Time

Product Dispensed

Flavor

Amount Dispensed

0913

SNUS

FROST

2

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

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



# CRF Report for Study E6210229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Week 10

Blank? N

CRF Page #: 14

Visit: WEEK 10

Visit Date: 26-06-2007

Document #: R158478113

Entered By: Cindy Prakop

Entry Time: 25-09-2007 10:48:33

CRF Status: Entry Complete

Discrepancies: Active

Modification Time: 30-11-2007 13:27:47

Approval Status: Not Approved

Approval Time:

Approver:

Verification: Not Verified

Verification Time:

Verifier:

Comment:

Section: Hdyl\_Oral\_Health

1 of 5

Blank? N

Section Status: Entry Complete

Visit: WEEK 10

Section Date: 26-06-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 10:48:33

Last Modification Time: 27-11-2007 23:26:38

Page number: 32

## HDYF? / ORAL HEALTH QUESTIONS INQUIRY

Actual Time	HDYF Performed?	Oral Health Questions Performed?	Comments
0823	YES	ND	

Section: Expired\_Carbon\_M

2 of 5

Blank? N

Section Status: Entry Complete

Visit: WEEK 10

Section Date: 26-06-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 10:48:33

Last Modification Time: 25-09-2007 10:59:32

Page number: 32

## EXPIRED CARBON MONOXIDE

Actual Time	ECO Level (ppm)	%COHb	Comments
0828	11	02.3	

Section: Vital

3 of 5

Blank? N

Section Status: Entry Complete

Visit: WEEK 10

Section Date: 26-06-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 10:48:33

Last Modification Time: 25-09-2007 10:59:32

Page number: 32

## VITAL SIGNS

Actual Time	Blood Pressure		Pulse	Respiratory Rate	Oral	Unit
	Systolic	Diastolic			Temperature	
0826	096	063	071	16	ND xxx.x	ND

Comments

Section: Unused\_Study\_Pro

4 of 5

Blank? N

Section Status: Entry Complete

# CRF Report for Study E6270229

Patient: 5004  
CRF: Week 10  
Visit: WEEK 10

Site: CA\_001  
Blank? N  
Visit Date: 26-06-2007

Investigator: C2785\_03  
CRF Page #: 14  
Document #: R158478113

Section: Unused\_Study\_Pro 4 of 5

Visit: WEEK 10

Entered By: Cindy Prakop

Section Date: 26-06-2007

Entry Time: 25-09-2007 10:48:33

Last Modification Time: 27-11-2007 23:26:57

Page number: 33

## Unused Study Product Returned

Product Returned	Flavor	Packs	Individual Cigarettes / pouches
ND	ND	ND	ND

Section: Study\_Prod\_Dispe 5 of 5

Visit: WEEK 10

Entered By: Cindy Prakop

Blank? N

Section Date: 26-06-2007

Entry Time: 25-09-2007 10:48:33

Last Modification Time: 25-09-2007 10:59:32

Page number: 33

Section Status: Entry Complete

## STUDY PRODUCT DISPENSATION

Actual Time	Product Dispensed	Flavor	Amount Dispensed
0830	SNUS	FROST	2

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

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

# CRF Report for Study E6210229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Week 12

Blank? N

CRF Page #: 15

Visit: WEEK 12

Visit Date: 09-07-2007

Document #: R158480413

Entered By: Cindy Prakop

Entry Time: 25-09-2007 10:59:38

CRF Status: Entry Complete

Discrepancies: Closed

Modification Time: 19-11-2007 10:29:21

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 12		Section Date: 09-07-2007	
Entered By: Cindy Prakop		Entry Time: 25-09-2007 10:59:38	
		Last Modification Time: 25-09-2007 11:10:10	
		Page number: 34	

## PRO QUESTIONNAIRES

Date		YES / NO
09-07-2007	1. With the possible exception of urinating, did subject complete Smoker Routine Questionnaire PRIOR to any study procedures being performed?	YES

Section: Urine_Drug	2 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 12		Section Date: 09-07-2007	
Entered By: Cindy Prakop		Entry Time: 25-09-2007 10:59:38	
		Last Modification Time: 25-09-2007 11:10:10	
		Page number: 34	

## Drug Screen

Date	Drug Screen Result
09-07-2007	NEG

Section: Alcohol_Screen	3 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 12		Section Date: 09-07-2007	
Entered By: Cindy Prakop		Entry Time: 25-09-2007 10:59:38	
		Last Modification Time: 25-09-2007 11:10:10	
		Page number: 34	

## Alcohol Screen

Date	Breathalyzer Result
09-07-2007	NEG

Section: Preg_Test	4 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 12		Section Date: 09-07-2007	
Entered By: Cindy Prakop		Entry Time: 25-09-2007 10:59:38	
		Last Modification Time: 14-11-2007 18:35:34	
		Page number: 34	

# CRF Report for Study E6270229

Patient: 5004  
CRF: Week 12  
Visit: WEEK 12

Site: CA\_001  
Blank? N  
Visit Date: 09-07-2007

Investigator: C2785\_03  
CRF Page #: 15  
Document #: R158480413

Section: Preg\_Test 4 of 11

Pregnancy Test  
Date  
09-07-2007  
Result  
N/A,  
MALE  
OR  
FEMA  
LE

Section: Urine\_Coll 5 of 11 Blank? N Section Status: Entry Complete  
Visit: WEEK 12 Section Date: 09-07-2007  
Entered By: Cindy Prakop Entry Time: 25-09-2007 10:59:38  
Last Modification Time: 14-11-2007 18:36:52  
Page number: 34

## 24-Hour Urine Collection

Scheduled Timepoint	Start Date	Start Time	Stop Date	Stop Time	Total Volume	Comments
SPOT URINE VOID	09-07-2007	1457	NA	NA	NA	
0 HOUR TO 24 HOURS	09-07-2007	1457	10-07-2007	1458	1150.5	

Section: Hdyf\_Oral\_Health 6 of 11 Blank? N Section Status: Entry Complete  
Visit: WEEK 12 Section Date: 09-07-2007  
Entered By: Cindy Prakop Entry Time: 25-09-2007 10:59:38  
Last Modification Time: 25-09-2007 11:10:10  
Page number: 35

## HDYF? INQUIRY

Date	Actual Time	HDYF Performed?	Comments
10-07-2007	0711	YES	

Section: Vital 7 of 11 Blank? N Section Status: Entry Complete  
Visit: WEEK 12 Section Date: 09-07-2007  
Entered By: Cindy Prakop Entry Time: 25-09-2007 10:59:38  
Last Modification Time: 25-09-2007 11:10:10  
Page number: 35

## VITAL SIGNS

Date	Actual Time	Blood Pressure		Pulse	Respiratory Rate	Oral	Unit
		Systolic	Diastolic			Temperature	
09-07-2007	1504	113	077	099	14	NA	NA

# CRF Report for Study E6210229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Week 12

Blank? N

CRF Page #: 15

Visit: WEEK 12

Visit Date: 09-07-2007

Document #: R158480413

Section: Vital 7 of 11

xxx.x

Comments

Section: Oral\_Health\_Exam 8 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 12

Section Date: 09-07-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 10:59:38

Last Modification Time: 25-09-2007 22:33:25

Page number: 35

## ORAL HEALTH EXAMINATION

Date

10-07-2007

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 12

Section Date: 09-07-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 10:59:38

Last Modification Time: 25-09-2007 11:10:10

Page number: 36

## PHYSICAL EXAMINATION

Date

10-07-2007

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

Section: Weight\_Height 10 of 11

Blank? N

Section Status: Entry Complete

# CRF Report for Study E6270229

Patient: 5004  
CRF: Week 12  
Visit: WEEK 12

Site: CA\_001  
Blank? N  
Visit Date: 09-07-2007

Investigator: C2785\_03  
CRF Page #: 15  
Document #: R158480413

Section: Weight\_Height 10 of 11

Visit: WEEK 12  
Entered By: Cindy Prakop

Section Date: 09-07-2007  
Entry Time: 25-09-2007 10:59:38  
Last Modification Time: 25-09-2007 11:10:10  
Page number: 36

## WEIGHT & HEIGHT

Date	Weight	Unit	Height	Unit
09-07-2007	048.6	KG	NA	
	xxx.x		xxx.x	

Section: Lab\_Eval 11 of 11

Visit: WEEK 12  
Entered By: Cindy Prakop

Blank? N  
Section Date: 09-07-2007  
Entry Time: 25-09-2007 10:59:38  
Last Modification Time: 25-09-2007 11:10:10  
Page number: 37

Section Status: Entry Complete

## Laboratory Evaluations

Date  
10-07-2007

Were the scheduled laboratory samples obtained? YES No, specify

Requisition Number 1 O850695  
Requisition Number 2 (if applicable) P150649

Were there any clinically significant labs? NO (Yes, specify below)

Requisition Number	Test Name	H/L	Lab ID	Lab Name
--------------------	-----------	-----	--------	----------

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

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

# CRF Report for Study E6210229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Week 12(2)

Blank? N

CRF Page #: 16

Visit: WEEK 12

Visit Date: 09-07-2007

Document #: R158485313

Entered By: Cindy Prakop

Entry Time: 25-09-2007 11:10:19

CRF Status: Entry Started

Discrepancies: None

Modification Time: 25-09-2007 23:15:55

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 12

Section Date: 09-07-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 11:10:19

Last Modification Time: 25-09-2007 11:21:47

Page number: 37

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

Date	Actual Time	Comments
10-07-2007	0713	

Section: Expired\_Carbon\_M

2 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 12

Section Date: 09-07-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 11:10:19

Last Modification Time: 25-09-2007 11:21:47

Page number: 37

EXPIRED CARBON MONOXIDE

Date	Actual Time	ECO Level (ppm)	%COHb	Comments
10-07-2007	1338	11	01.9	

Section: Blood\_Sampl\_Cohb

3 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 12

Section Date: 09-07-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 11:10:19

Last Modification Time: 25-09-2007 11:21:47

Page number: 37

Blood Sampling for %COHb

Date	Actual Time	Comments
10-07-2007	1342	

Section: Pre\_Bronch\_Spir

4 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 12

Section Date: 09-07-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 11:10:19

Last Modification Time: 25-09-2007 11:21:47

Page number: 38

# CRF Report for Study E6270229

Patient: 5004

CRF: Week 12(2)

Visit: WEEK 12

Site: CA\_001

Blank? N

Visit Date: 09-07-2007

Investigator: C2785\_03

CRF Page #: 16

Document #: R158485313

Section: Pre\_Bronch\_Spir 4 of 11

## PRE-BRONCHODILATOR BEST BASELINE SPIROMETRY TEST RESULT

Actual Time  
of FEV1/FVC

Date	Test	Testing Position	FEV1 L	FEV1 Predicted (%)	FVC L	FVC Predicted (%)	Comments
10-07-2007	1348	STANDI NG	2.42	84	3.83	110	

Section: Proventil\_Admin

5 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 12

Section Date: 09-07-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 11:10:19

Last Modification Time: 25-09-2007 11:21:47

Page number: 38

## PROVENTIL ADMINISTRATION

Actual Time  
of Proventil  
Administration

Date	Amount Administered	Comments
10-07-2007	1412	2 METERED PUFFS

Section: Post\_Bronch\_Spir

6 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 12

Section Date: 09-07-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 11:10:19

Last Modification Time: 25-09-2007 11:21:47

Page number: 38

## POST-BRONCHODILATOR BEST SPIROMETRY TEST RESULT

Actual Time  
of FEV1/FVC

Date	Test	Testing Position	FEV1 L	FEV1 Predicted (%)	FVC L	FVC Predicted (%)	Comments
10-07-2007	1427	STANDING	2.50	87	2.99	86	

Section: Used\_Study\_Tobac

7 of 11

Blank? Y

Section Status: Entry Complete

Visit: WEEK 12

Section Date: 09-07-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 11:10:19

Last Modification Time: 25-09-2007 23:15:55

Page number: 39

## USED STUDY TOBACCO-HEATING CIGARETTE COLLECTION

Scheduled Collection	Stop	Stop	Number of Study Tobacco-Heating Cigarettes	Weight of Cigarettes Collected	Any Product	If yes, # of other



# CRF Report for Study Eb270229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Week 12(2)

Blank? N

CRF Page #: 16

Visit: WEEK 12

Visit Date: 09-07-2007

Document #: R158485313

Section: Used\_Study\_Tobac 7 of 11

Timepoint	Start Date	Start Time	Date	Time	Collected	(g)	Deviation?	Brand	Comments
-----------	------------	------------	------	------	-----------	-----	------------	-------	----------

Section: Used\_Study\_Snus 8 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 12

Section Date: 09-07-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 11:10:19

Last Modification Time: 25-09-2007 11:21:47

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
	24 HOURS PRIOR TO CHECK-IN	08-07-2007	1450	09-07-2007	1450	17	NO	NA	
	24 HOURS IN-HOUSE	09-07-2007	1500	10-07-2007	1308	6	NO	NA	

Section: Used\_Study\_Burn 9 of 11

Blank? Y

Section Status: Entry Complete

Visit: WEEK 12

Section Date: 09-07-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 11:10:19

Last Modification Time: 25-09-2007 23:15:55

Page number: 41

## USED STUDY TOBACCO-BURNING CIGARETTE COLLECTION

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

Section: Used\_Butt\_Measur 10 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 12

Section Date: 09-07-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 11:10:19

Last Modification Time: 25-09-2007 11:21:47

Page number: 42

## USUAL STUDY TOBACCO-BURNING CIGARETTE BUTT MEASUREMENT

### Scheduled Collection

Date	Period
08-07-2007	24 HOURS PRIOR TO CHECK-IN

Cigarette Butt Number

Cigarette Butt Measurement (mm)

Section: Used\_Butt\_Measur 11 of 11

Blank? N

Section Status: Created

Visit: WEEK 12

Section Date: 09-07-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 11:10:19

# CRF Report for Study E6270229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Week 12(2)

Blank? N

CRF Page #: 16

Visit: WEEK 12

Visit Date: 09-07-2007

Document #: R158485313

Section: Used\_Butt\_Measur

11 of 11

Last Modification Time:

Page number: 43

## USED STUDY TOBACCO-BURNING CIGARETTE BUTT MEASUREMENT

Scheduled Collection

Date

Period

Cigarette Butt Number

Cigarette Butt Measurement (mm)

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

# CRF Report for Study E6270229

Patient: 5004

CRF: Week 12(3)

Visit: WEEK 12

Site: CA\_001

Blank? N

Visit Date: 09-07-2007

Investigator: C2785\_03

CRF Page #: 17

Document #: R158488813

Entered By: Cindy Prakop

Entry Time: 25-09-2007 11:21:48

CRF Status: Entry Complete

Discrepancies: Active

Modification Time: 30-11-2007 13:27:47

Approval Status: Not Approved

Approval Time:

Approver:

Verification: Not Verified

Verification Time:

Verifier:

Comment:

Section: Unused\_Study\_Pro

1 of 2

Blank? N

Section Status: Entry Complete

Visit: WEEK 12

Section Date: 09-07-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 11:21:48

Last Modification Time: 29-11-2007 21:49:02

Page number: 44

## Unused Study Product Returned

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

Section: Study\_Prod\_Dispe

2 of 2

Blank? N

Section Status: Entry Complete

Visit: WEEK 12

Section Date: 09-07-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 11:21:48

Last Modification Time: 25-09-2007 11:23:29

Page number: 44

## STUDY PRODUCT DISPENSATION

Date	Actual Time	Product Dispensed	Flavor	Amount Dispensed
10-07-2007	1440	SNUS	FROST	2

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

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

# CRF Report for Study EbZ70229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Week 14

Blank? N

CRF Page #: 18

Visit: WEEK 14

Visit Date: 24-07-2007

Document #: R158489413

Entered By: Cindy Prakop

Entry Time: 25-09-2007 11:23:30

CRF Status: Entry Complete

Discrepancies: Active

Modification Time: 28-11-2007 09:58:20

Approval Status: Not Approved

Approval Time:

Approver:

Verification: Not Verified

Verification Time:

Verifier:

Comment:

Section: Hdyl Oral Health

1 of 5

Blank? N

Section Status: Entry Complete

Visit: WEEK 14

Section Date: 24-07-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 11:23:30

Last Modification Time: 25-09-2007 11:59:25

Page number: 45

## HDYF? / ORAL HEALTH QUESTIONS INQUIRY

Actual Time	HDYF Performed?	Oral Health Questions Performed?	Comments
1500	YES	YES	

Section: Expired Carbon\_M

2 of 5

Blank? N

Section Status: Entry Complete

Visit: WEEK 14

Section Date: 24-07-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 11:23:30

Last Modification Time: 25-09-2007 11:59:25

Page number: 45

## EXPIRED CARBON MONOXIDE

Actual Time	ECO Level (ppm)	%COHb	Comments
1517	32	05.7	

Section: Vital

3 of 5

Blank? N

Section Status: Entry Complete

Visit: WEEK 14

Section Date: 24-07-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 11:23:30

Last Modification Time: 25-09-2007 11:59:25

Page number: 45

## VITAL SIGNS

Actual Time	Blood Pressure		Pulse	Respiratory Rate	Oral	Unit
	Systolic	Diastolic			Temperature	
1512	111	076	099	18	036.8	C
					xxx.x	

Comments

Section: Unused\_Study\_Pro

4 of 5

Blank? N

Section Status: Entry Complete

# CRF Report for Study E6270229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Week 14

Blank? N

CRF Page #: 18

Visit: WEEK 14

Visit Date: 24-07-2007

Document #: R158489413

Section: Unused\_Study\_Pro 4 of 5

Visit: WEEK 14

Entered By: Cindy Prakop

Section Date: 24-07-2007

Entry Time: 25-09-2007 11:23:30

Last Modification Time: 27-11-2007 23:27:57

Page number: 46

## Unused Study Product Returned

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

Section: Study\_Prod\_Dispe 5 of 5

Visit: WEEK 14

Entered By: Cindy Prakop

Blank? N

Section Status: Entry Complete

Section Date: 24-07-2007

Entry Time: 25-09-2007 11:23:30

Last Modification Time: 25-09-2007 11:59:25

Page number: 46

## STUDY PRODUCT DISPENSATION

Actual Time	Product Dispensed	Flavor	Amount Dispensed
1505	SNUS	FROST	2

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

# CRF Report for Study E6270229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Week 16

Blank? Y

CRF Page #: 19

Visit: WEEK 16

Visit Date: 17-08-2007

Document #: R158498813

Entered By: Cindy Prakop

Entry Time: 25-09-2007 11:59:30

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 16

Section Date: 17-08-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 11:59:30

Last Modification Time:

Page number: 47

## PRO QUESTIONNAIRES

With the possible exception of urinating, did subject  
complete Smoker Core Questionnaire PRIOR to any  
study procedures being performed?

YES / NO

Section: HDYF\_Oral\_Health

2 of 6

Blank? Y

Section Status: Created

Visit: WEEK 16

Section Date: 17-08-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 11:59:30

Last Modification Time:

Page number: 47

## HDYF? / ORAL HEALTH QUESTIONS INQUIRY

Oral Health

Questions

Actual Time

HDYF Performed?

Performed?

Comments

Section: Vital

3 of 6

Blank? Y

Section Status: Created

Visit: WEEK 16

Section Date: 17-08-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 11:59:30

Last Modification Time:

Page number: 47

## VITAL SIGNS

Blood Pressure

Actual Time

Systolic

Diastolic

Pulse

Respiratory Rate

Oral

Temperature

Unit

xxx.x

Comments

Section: Expired\_Carbon\_M

4 of 6

Blank? Y

Section Status: Created

Visit: WEEK 16

Section Date: 17-08-2007

# CRF Report for Study E6270229

Patient: 5004  
CRF: Week 16  
Visit: WEEK 16

Site: CA\_001  
Blank? Y  
Visit Date: 17-08-2007

Investigator: C2785\_03  
CRF Page #: 19  
Document #: R158498813

Section: Expired\_Carbon\_M 4 of 6

Entered By: Cindy Prakop

Entry Time: 25-09-2007 11:59:30

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: 17-08-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 11:59:30

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: 17-08-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 11:59:30

Last Modification Time:

Page number: 48

## STUDY PRODUCT DISPENSATION

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

# CRF Report for Study E6270229

Patient: 5004  
CRF: Week 18  
Visit: WEEK 18

Site: CA\_001  
Blank? Y  
Visit Date: 17-08-2007

Investigator: C2785\_03  
CRF Page #: 20  
Document #: R158505413  
CRF Status: Created

Entered By: Cindy Prakop  
Discrepancies: None  
Approval Status: Not Approved  
Verification: Not Verified  
Comment:

Entry Time: 25-09-2007 12:10:05  
Modification Time:  
Approval Time:  
Verification Time:

Approver:  
Verifier:

Section: Hdyf_Oral_Health	1 of 5	Blank? Y	Section Status: Created
Visit: WEEK 18		Section Date: 17-08-2007	
Entered By: Cindy Prakop		Entry Time: 25-09-2007 12:10:05	
		Last Modification Time:	
		Page number: 49	

## HDYF? / ORAL HEALTH QUESTIONS INQUIRY

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

Section: Expired_Carbon_M	2 of 5	Blank? Y	Section Status: Created
Visit: WEEK 18		Section Date: 17-08-2007	
Entered By: Cindy Prakop		Entry Time: 25-09-2007 12:10:05	
		Last Modification Time:	
		Page number: 49	

## EXPIRED CARBON MONOXIDE

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

Section: Vital	3 of 5	Blank? Y	Section Status: Created
Visit: WEEK 18		Section Date: 17-08-2007	
Entered By: Cindy Prakop		Entry Time: 25-09-2007 12:10:05	
		Last Modification Time:	
		Page number: 49	

## VITAL SIGNS

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

Section: Unused_Study_Pro	4 of 5	Blank? Y	Section Status: Created
Visit: WEEK 18		Section Date: 17-08-2007	
Entered By: Cindy Prakop		Entry Time: 25-09-2007 12:10:05	
		Last Modification Time:	



# CRF Report for Study E6270229

Patient: 5004  
CRF: Week 18  
Visit: WEEK 18

Site: CA\_001  
Blank? Y  
Visit Date: 17-08-2007

Investigator: C2785\_03  
CRF Page #: 20  
Document #: R158505413

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: 17-08-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:10:05

Last Modification Time:

Page number: 50

## STUDY PRODUCT DISPENSATION

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

# CRF Report for Study E6270229

Patient: 5004

CRF: Week 20

Visit: WEEK 20

Entered By: Cindy Prakop

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CA\_001

Blank? Y

Visit Date: 17-08-2007

Entry Time: 25-09-2007 12:10:23

Modification Time:

Approval Time:

Verification Time:

Investigator: C2785\_03

CRF Page #: 21

Document #: R158505513

CRF Status: Created

Approver:

Verifier:

Section: Pro\_Questionnair

1 of 6

Blank? Y

Section Status: Created

Visit: WEEK 20

Section Date: 17-08-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:10:23

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: 17-08-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:10:23

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: 17-08-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:10:23

Last Modification Time:

Page number: 51

## VITAL SIGNS

Actual Time

Blood Pressure

Systolic

Diastolic

Pulse

Respiratory Rate

Oral

Temperature

xxx.x

Unit

Comments

Section: Expired\_Carbon\_M

4 of 6

Blank? Y

Section Status: Created

Visit: WEEK 20

Section Date: 17-08-2007

# CRF Report for Study E6270229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Week 20

Blank? Y

CRF Page #: 21

Visit: WEEK 20

Visit Date: 17-08-2007

Document #: R158505513

Section: Expired\_Carbon\_M

4 of 6

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:10:23

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: 17-08-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:10:23

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: 17-08-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:10:23

Last Modification Time:

Page number: 52

## STUDY PRODUCT DISPENSATION

Actual Time

Product Dispensed

Flavor

Amount Dispensed

# CRF Report for Study Eb270229

Patient: 5004

CRF: Week 22

Visit: WEEK 22

Site: CA\_001

Blank? Y

Visit Date: 17-08-2007

Investigator: C2785\_03

CRF Page #: 22

Document #: R158505613

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:10:36

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 22

Section Date: 17-08-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:10:36

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: 17-08-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:10:36

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: 17-08-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:10:36

Last Modification Time:

Page number: 53

## VITAL SIGNS

Blood Pressure

Oral

Actual Time

Systolic

Diastolic

Pulse

Respiratory Rate

Temperature

Unit

xxx.x

Comments

Section: Unused\_Study\_Pro

4 of 5

Blank? Y

Section Status: Created

Visit: WEEK 22

Section Date: 17-08-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:10:36

Last Modification Time:

# CRF Report for Study Eb270229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Week 22

Blank? Y

CRF Page #: 22

Visit: WEEK 22

Visit Date: 17-08-2007

Document #: R158505613

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: 17-08-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:10:36

Last Modification Time:

Page number: 54

## STUDY PRODUCT DISPENSATION

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

# CRF Report for Study EbZ10229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Week 24 (Eos)

Blank? Y

CRF Page #: 23

Visit: WEEK 24 (EOS)

Visit Date: 17-08-2007

Document #: R158505713

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:10:46

CRF Status: Created

Discrepancies: None

Modification Time:

Approval Status: Not Approved

Approval Time:

Approver:

Verification: Not Verified

Verification Time:

Verifier:

Comment:

Section: Pro\_Questionnaire

1 of 12

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 17-08-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:10:46

Last Modification Time:

Page number: 55

## PRO QUESTIONNAIRES

Date

1. With the possible exception of urinating, did subject complete Smoker Routine Questionnaire PRIOR to any study procedures being performed?

YES / NO

Section: Urine\_Drug

2 of 12

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 17-08-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:10:46

Last Modification Time:

Page number: 55

## Drug Screen

Date

Drug Screen Result

Section: Alcohol\_Screen

3 of 12

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 17-08-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:10:46

Last Modification Time:

Page number: 55

## Alcohol Screen

Date

Breathalyzer Result

Section: Preg\_Test

4 of 12

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 17-08-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:10:46

Last Modification Time:

Page number: 55

## Pregnancy Test

# CRF Report for Study Eb270229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Week 24 (Eos)

Blank? Y

CRF Page #: 23

Visit: WEEK 24 (EOS)

Visit Date: 17-08-2007

Document #: R158505713

Section: Preg\_Test 4 of 12

Date Result

Section: Urine\_Coll 5 of 12

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 17-08-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:10:46

Last Modification Time:

Page number: 55

## 24-Hour Urine Collection

Scheduled Timepoint	Start Date	Start Time	Stop Date	Stop Time	Total Volume	Comments
---------------------	------------	------------	-----------	-----------	--------------	----------

Section: ECG 6 of 12

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 17-08-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:10:46

Last Modification Time:

Page number: 56

## 12-LEAD ELECTROCARDIOGRAM REPORT

Actual Time

Ventricular Heart Rate

Cardiac Cycle Measurements

PR Interval

QRS Duration

QT Interval

QTc Interval

ECG INTERPRETATION:

Comments (related to abnormal, CS findings only):

Section: Hdyf\_Oral\_Health 7 of 12

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 17-08-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:10:46

Last Modification Time:

Page number: 57

## HDYF? / ORAL HEALTH QUESTIONS INQUIRY

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

Section: Vital 8 of 12

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 17-08-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:10:46

Last Modification Time:

# CRF Report for Study EbZ10229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Week 24 (Eos)

Blank? Y

CRF Page #: 23

Visit: WEEK 24 (EOS)

Visit Date: 17-08-2007

Document #: R158505713

Section: Vital

8 of 12

Page number: 57

## VITAL SIGNS

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

Section: Oral\_Health\_Exam

9 of 12

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 17-08-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:10:46

Last Modification Time:

Page number: 57

## ORAL HEALTH EXAMINATION

Date	Procedure	Relevant Findings?	Findings
------	-----------	--------------------	----------

Section: Phys\_Exam

10 of 12

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 17-08-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:10:46

Last Modification Time:

Page number: 58

## PHYSICAL EXAMINATION

Date	Code Number	Code	Relevant Findings?	Findings
------	-------------	------	--------------------	----------

Section: Weight\_Height

11 of 12

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 17-08-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:10:46

Last Modification Time:

Page number: 58

## WEIGHT & HEIGHT

Date	Weight xxx.x	Unit	Height xxx.x	Unit
------	-----------------	------	-----------------	------

Section: Lab\_Eval

12 of 12

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 17-08-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:10:46



# CRF Report for Study E6270229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Week 24 (Eos)

Blank? Y

CRF Page #: 23

Visit: WEEK 24 (EOS)

Visit Date: 17-08-2007

Document #: R158505713

Section: Lab\_Eval

12 of 12

Last Modification Time:

Page number: 59

## Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

No, specify

Requisition Number 1

Requisition Number 2 (if applicable)

Were there any clinically significant labs?

(Yes, specify below)

Requisition Number

Test Name

H/L

Lab ID

Lab Name

# CRF Report for Study Eb210229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Week 24-2 (Eos)

Blank? Y

CRF Page #: 24

Visit: WEEK 24 (EOS)

Visit Date: 17-08-2007

Document #: R158505813

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:11:00

CRF Status: Created

Discrepancies: None

Modification Time:

Approval Status: Not Approved

Approval Time:

Approver:

Verification: Not Verified

Verification Time:

Verifier:

Comment:

Section: Pk\_Blood\_Biomark

1 of 11

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 17-08-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:11:00

Last Modification Time:

Page number: 59

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

Date

Actual Time

Comments

Section: Expired\_Carbon\_M

2 of 11

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 17-08-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:11:00

Last Modification Time:

Page number: 59

EXPIRED CARBON MONOXIDE

Date

Actual Time

ECO Level (ppm)

%COHb

Comments

Section: Blood\_Sampl\_Cohb

3 of 11

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 17-08-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:11:00

Last Modification Time:

Page number: 59

Blood Sampling for %COHb

Date

Actual Time

Comments

Section: Pre\_Bronch\_Spir

4 of 11

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 17-08-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:11:00

Last Modification Time:

Page number: 60

PRE-BRONCHODILATOR BEST BASELINE SPIROMETRY TEST RESULT

Actual Time

# CRF Report for Study E6270229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Week 24-2 (Eos)

Blank? Y

CRF Page #: 24

Visit: WEEK 24 (EOS)

Visit Date: 17-08-2007

Document #: R158505813

Section: Pre\_Bronch\_Spir 4 of 11

Date	of FEV1/FVC Test	Testing Position	FEV1 L	FEV1 Predicted (%)	FVC L	FVC Predicted (%)	Comments
------	---------------------	---------------------	--------	--------------------	-------	----------------------	----------

Section: Proventil\_Admin 5 of 11

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 17-08-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:11:00

Last Modification Time:

Page number: 60

## PROVENTIL ADMINISTRATION

Actual Time  
of Proventil

Date	Administration	Amount Administered	Comments
------	----------------	---------------------	----------

Section: Post\_Bronch\_Spir 6 of 11

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 17-08-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:11:00

Last Modification Time:

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
------	------	---------------------	--------	--------------------	-------	-------------------	----------

Section: Used\_Study\_Tobac 7 of 11

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 17-08-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:11:00

Last Modification Time:

Page number: 61

## USED STUDY TOBACCO-HEATING CIGARETTE COLLECTION

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

Section: Used\_Study\_Snus 8 of 11

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 17-08-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:11:00

# CRF Report for Study E6270229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Week 24-2 (Eos)

Blank? Y

CRF Page #: 24

Visit: WEEK 24 (EOS)

Visit Date: 17-08-2007

Document #: R158505813

Section: Used\_Study\_Snus

8 of 11

Last Modification Time:

Page number: 62

## USED STUDY SNUS COLLECTION

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

Section: Used\_Study\_Burn

9 of 11

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 17-08-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:11:00

Last Modification Time:

Page number: 63

## USED STUDY TOBACCO-BURNING CIGARETTE COLLECTION

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

Section: Used\_Butt\_Measur

10 of 11

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 17-08-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:11:00

Last Modification Time:

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: 17-08-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:11:00

Last Modification Time:

Page number: 65

## USED STUDY TOBACCO-BURNING CIGARETTE BUTT MEASUREMENT

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

# CRF Report for Study E6270229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Week 24-3

Blank? Y

CRF Page #: 25

Visit: WEEK 24 (EOS)

Visit Date: 17-08-2007

Document #: R158505913

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:11:11

CRF Status: Created

Discrepancies: None

Modification Time:

Approver:

Approval Status: Not Approved

Approval Time:

Verifier:

Verification: Not Verified

Verification Time:

Comment:

Section: Unused\_Study\_Pro

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 17-08-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:11:11

Last Modification Time:

Page number: 65A

## Unused Study Product Returned

### Amount Returned

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

# CRF Report for Study E6270229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Precon\_Med

Blank? N

CRF Page #: 26

Visit: PRECON\_MEDS

Visit Date: 17-08-2007

Document #: R158506013

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:11:25

CRF Status: Entry Complete

Discrepancies: None

Modification Time: 25-09-2007 12:11:54

Approval Status: Not Approved

Approval Time:

Approver:

Verification: Not Verified

Verification Time:

Verifier:

Comment:

Section: Pre\_Conmed

Blank? N

Section Status: Entry Complete

Visit: PRECON\_MEDS

Section Date: 17-08-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:11:25

Last Modification Time: 25-09-2007 12:11:54

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

		Dose /									
Seq #	Drug Name	Indication	Dose Unit	Route	Specify	Freq	Specify	Start Date	Stop Date/Ongoing		

# CRF Report for Study Eb270229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: AE

Blank? N

CRF Page #: 27

Visit: AE

Visit Date: 17-08-2007

Document #: R158506113

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:11:55

CRF Status: Entry Complete

Discrepancies: None

Modification Time: 25-09-2007 12:12:37

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: 17-08-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:11:55

Last Modification Time: 25-09-2007 12:12:37

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 E6210229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Ecg\_Unscheduled

Blank? Y

CRF Page #: 28

Visit: ECG\_UNSCHEDED

Visit Date: 17-08-2007

Document #: R158506413

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:12:38

CRF Status: Created

Discrepancies: None

Modification Time:

Approver:

Approval Status: Not Approved

Approval Time:

Verifier:

Verification: Not Verified

Verification Time:

Comment:

Section: ECG

Blank? Y

Section Status: Created

Visit: ECG\_UNSCHEDED

Section Date: 17-08-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:12:38

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 EbZ70229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Lab\_Unscheduled

Blank? Y

CRF Page #: 29

Visit: LAB\_UNSCHEd

Visit Date: 17-08-2007

Document #: R158506613

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:12:48

CRF Status: Created

Discrepancies: None

Modification Time:

Approver:

Approval Status: Not Approved

Approval Time:

Verifier:

Verification: Not Verified

Verification Time:

Comment:

Section: Lab\_Eval

Blank? Y

Section Status: Created

Visit: LAB\_UNSCHEd

Section Date: 17-08-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:12:48

Last Modification Time:

Page number: 69

## Unscheduled Laboratory Evaluations

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

# CRF Report for Study E6270229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Vital\_Unscheduled

Blank? N

CRF Page #: 30

Visit: VITAL\_UNSCHE

Visit Date: 30-04-2007

Document #: R157988913

Entered By: Ben Heyen

Entry Time: 21-09-2007 13:55:53

CRF Status: Entry Complete

Discrepancies: None

Modification Time: 21-09-2007 13:58:14

Approver:

Approval Status: Not Approved

Approval Time:

Verifier:

Verification: Not Verified

Verification Time:

Comment:

Section: Vital

Blank? N

Section Status: Entry Complete

Visit: VITAL\_UNSCHE

Section Date: 30-04-2007

Entered By: Ben Heyen

Entry Time: 21-09-2007 13:55:53

Last Modification Time: 21-09-2007 13:58:14

Page number: 70

## UNSCHEDULED VITAL SIGNS

Date	Actual Time	Blood Pressure		Pulse	Respiratory Rate	Oral Temperature xxx.x	Unit	Comments
		Systolic	Diastolic					
30-04-2007	0851	096	61	NA	NA	NA	NA	

# CRF Report for Study E6270229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Stdy\_Prdt\_Dis\_Unschedulec

Blank? Y

CRF Page #: 31

Visit: STDY\_PRDT\_UNSCHE

Visit Date: 17-08-2007

Document #: R158507013

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:13:00

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: 17-08-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:13:00

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: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Expired\_CO2\_Unscheduled

Blank? Y

CRF Page #: 32

Visit: EXPIRED\_CO2\_UNSC

Visit Date: 17-08-2007

Document #: R158507713

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:14:29

CRF Status: Created

Discrepancies: None

Modification Time:

Approval Status: Not Approved

Approval Time:

Approver:

Verification: Not Verified

Verification Time:

Verifier:

Comment:

Section: Expired\_Carbon\_M

Blank? Y

Section Status: Created

Visit: EXPIRED\_CO2\_UNSC

Section Date: 17-08-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:14:29

Last Modification Time:

Page number: 72

## UNSCHEDULED EXPIRED CARBON MONOXIDE

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

# CRF Report for Study E6270229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Oral\_Health\_Unscheduled

Blank? Y

CRF Page #: 33

Visit: ORAL\_HEALTH\_UNSC

Visit Date: 17-08-2007

Document #: R158507813

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:14:38

CRF Status: Created

Discrepancies: None

Modification Time:

Approver:

Approval Status: Not Approved

Approval Time:

Verifier:

Verification: Not Verified

Verification Time:

Comment:

Section: Oral\_Health\_Exam

Blank? Y

Section Status: Created

Visit: ORAL\_HEALTH\_UNSC

Section Date: 17-08-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:14:38

Last Modification Time:

Page number: 73

## UNSCHEDULED ORAL HEALTH EXAMINATION

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

# CRF Report for Study E6270229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Spirometry\_Unscheduled

Blank? Y

CRF Page #: 34

Visit: SPIRO\_TEST\_UNSCH

Visit Date: 17-08-2007

Document #: R158507913

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:14:47

CRF Status: Created

Discrepancies: None

Modification Time:

Approver:

Approval Status: Not Approved

Approval Time:

Verifier:

Verification: Not Verified

Verification Time:

Comment:

Section: Pre\_Bronch\_Spir

Blank? Y

Section Status: Created

Visit: SPIRO\_TEST\_UNSCH

Section Date: 17-08-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:14:47

Last Modification Time:

Page number: 74

## UNSCHEDULED SPIROMETRY TEST RESULT

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

# CRF Report for Study Eb270229

Patient: 5004

Site: CA\_001

Investigator: C2785\_03

CRF: Study\_Completion

Blank? N

CRF Page #: 35

Visit: STUDY\_COMP

Visit Date: 17-08-2007

Document #: R158508113

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:14:57

CRF Status: Entry Complete

Discrepancies: None

Modification Time: 25-09-2007 12:17:51

Approval Status: Not Approved

Approval Time:

Approver:

Verification: Not Verified

Verification Time:

Verifier:

Comment:

Section: Study\_Comp

Blank? N

Section Status: Entry Complete

Visit: STUDY\_COMP

Section Date: 17-08-2007

Entered By: Cindy Prakop

Entry Time: 25-09-2007 12:14:57

Last Modification Time: 25-09-2007 12:17:51

Page number: 75

## Study Completion

Did the subject complete the study?

NO

Date the subject completed OR withdrew from the study:

17-08-2007

Reason for Withdrawal

OTH

Specify

SUBJECT DROPPED NON- COMPLIANCE

Investigator Comments

Principal Investigator

*Doris Carter MP* Date 20 Dec 07

**Covance CLS**

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

**LABORATORY REPORT**

ACCESSION NO. 0062460

Page 1 of 3

INVESTIGATOR: (B17181)

David Carter, M.D.  
c/o Marianna Alesi  
Covance-Austin  
313 East Anderson Lane #200  
Austin, TX 78752

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.: 5

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME: 11:25 DATE: 26-Mar-2007

DATE RECEIVED IN LABORATORY: 27-Mar-2007

DATE REPORTED BY LABORATORY: 27-Mar-2007

SEX: F BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5018

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

## CHEMISTRY PANEL

Total Bili	0.4		0.2-1.2 mg/dL
Alk Phos	108	H	31-106 U/L
ALT (SGPT)	10		6-34 U/L
AST (SGOT)	13		9-34 U/L
GGT	31		4-49 U/L
LDH	143		53-234 U/L
Urea Nitr	8		4-24 mg/dL
Creatinine	0.8		0.4-1.1 mg/dL
Glucose	86		70-115 mg/dL
Uric Acid	3.5		2.1-7.2 mg/dL
Calcium	9.7		8.3-10.6 mg/dL
Phosphorus	3.4		2.2-5.1 mg/dL
Total Prot	7.6		6.1-8.4 g/dL
Albumin	4.5		3.3-4.9 g/dL
Sodium	142		132-147 mEq/L
Potassium	3.7		3.4-5.4 mEq/L
Chloride	105		94-112 mEq/L

[ ]

[x]

Investigator Signature:

3-29-07

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

B17181

(INV)



**Covance CLS**

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

**LABORATORY REPORT**

ACCESSION NO. 0062460

Page 2 of 3

## INVESTIGATOR: (B17181)

David Carter, M.D.  
c/o Marianna Alesi  
Covance-Austin  
313 East Anderson Lane #200  
Austin, TX 78752

PROTOCOL 6270-229

INVESTIGATOR NO.: 5

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

## SPONSOR REPORT TO:

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

Screen

COLLECTION TIME: 11:25 DATE: 26-Mar-2007

DATE RECEIVED IN LABORATORY: 27-Mar-2007

DATE REPORTED BY LABORATORY: 27-Mar-2007

SEX: F BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5018

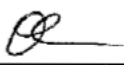
Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

## HEMATOLOGY&amp; DIFFERENTIAL PANEL

HGB	13.3	11.6-16.4 g/dL
HCT	41	34-48 %
RBC	4.4	4.1-5.6x10 <sup>6</sup> /uL
MCV	92	79-98 fL
MCH	30	26-34 pg
MCHC	33	31-38 g/dL
RDW	14.1	12.0-15.0 %
RBC Morph	Normocytic	
WBC	8.61	3.80-10.70 x10 <sup>3</sup> /uL
Neutrophil	5.77	1.96-7.23 x10 <sup>3</sup> /uL
Lymphocyte	2.17	0.91-4.28 x10 <sup>3</sup> /uL
Monocytes	0.57	0.12-0.92 x10 <sup>3</sup> /uL
Eosinophil	0.06	0.00-0.57 x10 <sup>3</sup> /uL
Basophils	0.03	0.00-0.20 x10 <sup>3</sup> /uL
Neutrophil	67.1	40.5-75.0 %
Lymphocyte	25.2	15.4-48.5%
Monocytes	6.7	2.6-10.1 %
Eosinophil	0.8	0.0-6.8 %
Basophils	0.4	0.0-2.0 %
Platelets	247	140-400 x10 <sup>3</sup> /uL

  
Investigator Signature:

3-29-07

Date:

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

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

(INV)

**Covance CLS**

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**LABORATORY REPORT**

ACCESSION NO. 0062460

Page 3 of 3

## INVESTIGATOR: (B17181)

David Carter, M.D.  
c/o Marianna Alesi  
Covance-Austin  
313 East Anderson Lane #200  
Austin, TX 78752

PROTOCOL 6270-229  
INVESTIGATOR NO.: 5  
RANDOMIZATION NUMBER:  
PATIENT INITIALS: (b) (6)  
VISIT: 1

## SPONSOR REPORT TO:

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

Screen

COLLECTION TIME: 11:25 DATE: 26-Mar-2007  
DATE RECEIVED IN LABORATORY: 27-Mar-2007  
DATE REPORTED BY LABORATORY: 27-Mar-2007  
SEX: F BIRTHDATE: (b) (6) AGE: 36  
SCREENING NUMBER: S5018

Is this Clinically  
Significant/ Adverse  
Event?

Yes No

## URINE MACRO &amp; MICRO PANEL

Color	Yellow	Ref Rng:	
		Colorless or Yellow	
Clarity	Hazy	Ref Rng: Clear	
Spec Grav	1.008	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-Trace	
Nitrite	+1 H	Ref Rng: Negative	[ ] [X]
Leuk Est	Negative	Ref Rng: Negative	
Microscop	Positive <i>WCS</i>		

## CELLULAR ELEMENTS

WBC 1 0-12 /HPF

*gc*  
Investigator Signature:

*3-29-07*  
Date:

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

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**LABORATORY REPORT**

ACCESSION NO. 0062460

Page 1 of 1

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313 East Anderson Lane #200  
Austin, TX 78752

SPONSOR REPORT TO:

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

PROTOCOL 6270-229

INVESTIGATOR NO.: 5

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME: 11:25 DATE: 26-Mar-2007

DATE RECEIVED IN LABORATORY: 27-Mar-2007

DATE REPORTED BY LABORATORY: 27-Mar-2007

SEX: F BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5018

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

TOTAL IRON

Total Iron 43 30-160 ug/dL

FOLLICLE STIMULATING HORMONE

FSH 4.2

Follicular:

4.0-13.0 mIU/mL

Mid-Cycle:

5.0-22.0 mIU/mL

Luteal:

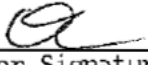
2.0-13.0 mIU/mL

Postmenopausal:

20.0-138.0 mIU/mL

HEPATITIS A ANTIBODY-IGM

HepA IgMab Negative No Ref Rng

  
Investigator Signature:

3-29-07  
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

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**LABORATORY REPORT**

ACCESSION NO. 0062460

Page 1 of 1

INVESTIGATOR: (B17181)

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Covance-Austin  
313 East Anderson Lane #200  
Austin, TX 78752

PROTOCOL 6270-229

INVESTIGATOR NO.: 5

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

SPONSOR REPORT TO:

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

Screen

COLLECTION TIME: 11:25 DATE: 26-Mar-2007

DATE RECEIVED IN LABORATORY: 27-Mar-2007

DATE REPORTED BY LABORATORY: 27-Mar-2007

SEX: F BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5018

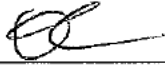
Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

HIV 1/HIV 2 ANTIBODY SCREEN

HIV-1/2 Non-Reactive Reference Range:  
Non-Reactive

  
Investigator Signature:13-29-07  
Date:

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

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**LABORATORY REPORT**

ACCESSION NO. 0062460

Page 1 of 1

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Covance-Austin  
313 East Anderson Lane #200  
Austin, TX 78752

**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.: 5

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME: 11:25 DATE: 26-Mar-2007

DATE RECEIVED IN LABORATORY: 27-Mar-2007

DATE REPORTED BY LABORATORY: 27-Mar-2007

SEX: F BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5018


Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

**HEPATITIS B CORE ANTIBODY-IGM**

Hep Bc IgM      Negative      Ref Rng: Negative

  
Investigator Signature:

3-29-07

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

B17181

(INV)

**Covance CLS**

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

**LABORATORY REPORT**

ACCESSION NO. 0062460

Page 1 of 1

INVESTIGATOR: (B17181)

David Carter, M.D.

c/o Marianna Alesi

Covance-Austin

313 East Anderson Lane #200

Austin, TX 78752

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.: 5

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME: 11:25 DATE: 26-Mar-2007

DATE RECEIVED IN LABORATORY: 27-Mar-2007

DATE REPORTED BY LABORATORY: 27-Mar-2007

SEX: F BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5018

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:

3-29-07  
Date:

B17181

(INV)

**Covance CLS**

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

**LABORATORY REPORT**

ACCESSION NO. 0062460

Page 1 of 1

INVESTIGATOR: (B17181)

David Carter, M.D.  
c/o Marianna Alesi  
Covance-Austin  
313 East Anderson Lane #200  
Austin, TX 78752

PROTOCOL 6270-229  
INVESTIGATOR NO.: 5  
RANDOMIZATION NUMBER:  
PATIENT INITIALS: (b) (6)  
VISIT: 1

SPONSOR REPORT TO:

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

Screen

COLLECTION TIME: 11:25 DATE: 26-Mar-2007  
DATE RECEIVED IN LABORATORY: 27-Mar-2007  
DATE REPORTED BY LABORATORY: 28-Mar-2007  
SEX: F BIRTHDATE: (b) (6) AGE: 36  
SCREENING NUMBER: S5018

Is this Clinically  
Significant/ Adverse  
Event?

Yes No

HEPATITIS B SURFACE ANTIGEN

HBSAG Negative No Ref Rng

HEPATITIS C VIRUS ANTIBODY


ANTI-HCV Negative No Ref Rng

HEPATITIS B SURFACE ANTIBODY

HBSAB Negative No Ref Rng

ESTRADIOL

Estradiol 80.9 pg/mL  
See Inv. Manual

  
Investigator Signature:

01 Apr 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

B17181

(INV)

**Covance CLS**

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

**LABORATORY REPORT**

ACCESSION NO. N528366

Page 1 of 1

INVESTIGATOR: (B17181)

David Carter, M.D.

c/o Marianna Alesi

Covance-Austin

313 East Anderson Lane #200

Austin, TX 78752

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.: 5

RANDOMIZATION NUMBER: R5018

PATIENT INITIALS: (b) (6)

VISIT: 24 HR UR

24 Hr Urine Collection

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

DATE RECEIVED IN LABORATORY: 17-Apr-2007

DATE REPORTED BY LABORATORY: 25-Apr-2007

SEX: F BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5004

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

URINE CREATININE, 24 HR

U24h Creat

579

L

600-1600 mg/24hr

UALq24Crea

87.8

mg/dL No Ref Rng

[ ]

[X]

ELAPSED DATE AND TIME, 24HR

Elpsd D&amp;T

1440

min

24 HR COLLECTION INFORMATION

Start Date

15-Apr-2007

Start Time

15:45

Stop Date

16-Apr-2007

Stop Time

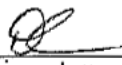
15:45

TOTAL 24HR URINE VOLUME

Total Vol.

660

mL

  
Investigator Signature:

28 Apr 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

B17181

(INV)



**Covance CLS**

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**LABORATORY REPORT**

ACCESSION NO. 0062482

Page 1 of 1

## INVESTIGATOR: (B17181)

David Carter, M.D.  
c/o Marianna Alesi  
Covance-Austin  
313 East Anderson Lane #200  
Austin, TX 78752

PROTOCOL 6270-229

INVESTIGATOR NO.: 5

RANDOMIZATION NUMBER: R5018

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: 15:29 DATE: 15-Apr-2007

DATE RECEIVED IN LABORATORY: 16-Apr-2007

DATE REPORTED BY LABORATORY: 26-Apr-2007

SEX: F BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5004

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

sICAM-1

sICAM-1


494

H

115-306 ng/mL

[ ]

[X]

  
Investigator Signature:

28 Apr 07  
Date:

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ACCESSION NO. 0062482

Page 1 of 1

INVESTIGATOR: (B17181)

David Carter, M.D.  
 c/o Marianna Alesi  
 Covance-Austin  
 313 East Anderson Lane #200  
 Austin, TX 78752

PROTOCOL 6270-229  
 INVESTIGATOR NO.: 5  
 RANDOMIZATION NUMBER: R5004  
 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: 15:29 DATE: 15-Apr-2007  
 DATE RECEIVED IN LABORATORY: 16-Apr-2007  
 DATE REPORTED BY LABORATORY: 20-Apr-2007  
 SEX: F BIRTHDATE: (b) (6) AGE: 36  
 SCREENING NUMBER: S5018

Is this Clinically  
 Significant/ Adverse  
 Event?

Yes

No

**CHEMISTRY PANEL**

Total Bili	0.2		0.2-1.2 mg/dL
Alk Phos	114	H	31-106 U/L
ALT (SGPT)	14		6-34 U/L
AST (SGOT)	18		9-34 U/L
GGT	36		4-49 U/L
LDH	132		53-234 U/L
Urea Nitr	14		4-24 mg/dL
Creatinine	0.9		0.4-1.1 mg/dL
Glucose	96		70-115 mg/dL
Uric Acid	3.9		2.1-7.2 mg/dL
Calcium	9.8		8.3-10.6 mg/dL
Phosphorus	4.0		2.2-5.1 mg/dL
Total Prot	7.4		6.1-8.4 g/dL
Albumin	4.1		3.3-4.9 g/dL
Sodium	141		132-147 mEq/L
Potassium	4.2		3.4-5.4 mEq/L
Chloride	105		94-112 mEq/L

[ ]

[✓] LB

*Linda Bartolomea/Far* OC  
 Investigator Signature:

11 Jun 07

04/23/07

Date:

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(INV)

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**LABORATORY REPORT**

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Page 1 of 1

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313 East Anderson Lane #200

Austin, TX 78752

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.: 5

RANDOMIZATION NUMBER: R5004

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 15:29 DATE: 15-Apr-2007

DATE RECEIVED IN LABORATORY: 16-Apr-2007

DATE REPORTED BY LABORATORY: 20-Apr-2007

SEX: F BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5018

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

HOMOCYSTEINE

\*1 HCY

8.35

3.36-20.44 umol/L

VIB

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.

Investigator Signature:



11 Jun 07

04/23/07

Date:

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313 East Anderson Lane #200  
Austin, TX 78752

PROTOCOL 6270-229

INVESTIGATOR NO.: 5

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 2

## SPONSOR REPORT TO:

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

Week 0

COLLECTION TIME: 15:29 DATE: 15-Apr-2007

DATE RECEIVED IN LABORATORY: 16-Apr-2007

DATE REPORTED BY LABORATORY: 16-Apr-2007

SEX: F BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5018

Is this Clinically  
Significant/ Adverse  
Event?


Yes

No

HAS PATIENT FASTED 8 HOURS?

Fasted?

Yes

  
Investigator Signature:

11 Jun 07  
Date:

B17181

(INV)

**Covance CLS**

Marietta Henry, M.D., Director  
 8211 SciCor Drive - Indianapolis, IN 46214-2985  
 Tel. +1 (800) 327 7279  
**LABORATORY REPORT**

ACCESSION NO. 0062482

Page 1 of 1

INVESTIGATOR: (B17181)

David Carter, M.D.  
 c/o Marianna Alesi  
 Covance-Austin  
 313 East Anderson Lane #200  
 Austin, TX 78752

PROTOCOL 6270-229  
 INVESTIGATOR NO.: 5  
 RANDOMIZATION NUMBER:  
 PATIENT INITIALS: (b) (6)  
 VISIT: 2

SPONSOR REPORT TO:

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

Week 0

COLLECTION TIME: 15:29 DATE: 15-Apr-2007  
 DATE RECEIVED IN LABORATORY: 16-Apr-2007  
 DATE REPORTED BY LABORATORY: 17-Apr-2007  
 SEX: F BIRTHDATE: (b) (6) AGE: 36  
 SCREENING NUMBER: S5018

Is this Clinically  
 Significant/ Adverse  
 Event?  
 Yes No

CHEMISTRY PANEL - See Note #1

HEMATOLOGY&amp; DIFFERENTIAL PANEL - See Note #1

URINE MACRO &amp; MICRO PANEL

Color	Yellow	Ref Rng:	
		Colorless or Yellow	
Clarity	Hazy	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-Trace	
Nitrite	+2 H	Ref Rng:Negative	[ ] [✓]
Leuk Est	Negative	Ref Rng:Negative	
Microscop	Positive <i>pus</i>		

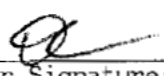
CELLULAR ELEMENTS

WBC	1	0-12 /HPF
Squam Epi	1	0-3 /HPF

MICROORGANISMS

Bacteria	Present <i>pus</i>	Ref Rng:Not present
----------	--------------------	---------------------

Note #1 - No specimen received

Investigator Signature: 18 Apr 07  
Date:

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B17181

(INV)

**Covance CLS**

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Tel. #1 (800) 327 7270

**LABORATORY REPORT**

ACCESSION NO. 0062482

Page 1 of 1

**INVESTIGATOR: (B17181)**

David Carter, M.D.  
c/o Marianna Alesi  
Covance-Austin  
313 East Anderson Lane #200  
Austin, TX 78752

PROTOCOL 6270-229

INVESTIGATOR NO.: 5

RANDOMIZATION NUMBER: R5004

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: 15:29 DATE: 15-Apr-2007

DATE RECEIVED IN LABORATORY: 16-Apr-2007

DATE REPORTED BY LABORATORY: 19-Apr-2007

SEX: F BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5018

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

**HEMATOLOGY& DIFFERENTIAL PANEL**

HGB	13.2	11.6-16.4 g/dL
HCT	41	34-48 %
RBC	4.3	4.1-5.6x10 <sup>6</sup> /uL
MCV	95	79-98 fL
MCH	31	26-34 pg
MCHC	32	31-38 g/dL
RDW	13.7	12.0-15.0 %
RBC Morph	Normocytic	
WBC	8.95	3.80-10.70 x10 <sup>3</sup> /uL
Neutrophil	5.21	1.96-7.23 x10 <sup>3</sup> /uL
Lymphocyte	2.99	0.91-4.28 x10 <sup>3</sup> /uL
Monocytes	0.59	0.12-0.92 x10 <sup>3</sup> /uL
Eosinophil	0.14	0.00-0.57 x10 <sup>3</sup> /uL
Basophils	0.03	0.00-0.20 x10 <sup>3</sup> /uL
Neutrophil	58.2	40.5-75.0 %
Lymphocyte	33.3	15.4-48.5 %
Monocytes	6.6	2.6-10.1 %
Eosinophil	1.5	0.0-6.8 %
Basophils	0.4	0.0-2.0 %
Platelets	255	140-400 x10 <sup>3</sup> /uL

Investigator Signature:

19 Apr 07  
Date:

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B17181

(INV)

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**LABORATORY REPORT**

ACCESSION NO. 0062482

Page 1 of 1

**INVESTIGATOR: (B17181)**

David Carter, M.D.  
c/o Marianna Alesi  
Covance-Austin  
313 East Anderson Lane #200  
Austin, TX 78752

**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.: 5  
RANDOMIZATION NUMBER: R5004  
PATIENT INITIALS: (b) (6)  
VISIT: 2

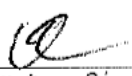
Week 0

COLLECTION TIME: 15:29 DATE: 15-Apr-2007  
DATE RECEIVED IN LABORATORY: 16-Apr-2007  
DATE REPORTED BY LABORATORY: 19-Apr-2007  
SEX: F BIRTHDATE: (b) (6) AGE: 36  
SCREENING NUMBER: S5018

Is this Clinically  
Significant/ Adverse  
Event?

Yes No

RBC CELL WASHING (4-ABP-HB)  
Wash/Store Completed

  
Investigator Signature:

19 Apr 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

B17181

(INV)

**Covance CLS**

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

**LABORATORY REPORT**

ACCESSION NO. 0062482

Page 1 of 1

INVESTIGATOR: (B17181)

David Carter, M.D.  
c/o Marianna Alesi  
Covance-Austin  
313 East Anderson Lane #200  
Austin, TX 78752

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.: 5

RANDOMIZATION NUMBER: R5004

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 15:29 DATE: 15-Apr-2007

DATE RECEIVED IN LABORATORY: 15-Apr-2007

DATE REPORTED BY LABORATORY: 19-Apr-2007

SEX: F BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5018

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

HEMOGLOBIN A1C


Hgb A1c 5.6

Normals:

4.3-6.1%

Stable Diabetics:

4.2-11.2%

  
Investigator Signature:

19 Apr 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

B17181

(INV)



**Covance CLS**

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Tel. +1 (800) 327 7270

**LABORATORY REPORT**

ACCESSION NO. 0062482

Page 1 of 1

**INVESTIGATOR: (B17181)**

David Carter, M.D.  
c/o Marianna Alesi  
Covance-Austin  
313 East Anderson Lane #200  
Austin, TX 78752

PROTOCOL 6270-229  
INVESTIGATOR NO.: 5  
RANDOMIZATION NUMBER: R5004  
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: 15:29 DATE: 15-Apr-2007  
DATE RECEIVED IN LABORATORY: 16-Apr-2007  
DATE REPORTED BY LABORATORY: 19-Apr-2007  
SEX: F BIRTHDATE: (b) (6) AGE: 36  
SCREENING NUMBER: S5018

Is this Clinically  
Significant/ Adverse  
Event?

Yes No

**LIPID PANEL**

Triglycer	137	39-176 mg/dL
Cholest	190	141-240 mg/dL
HDL Dex-S	35	34-82 mg/dL
LDL Chol	128	75-172 mg/dL

  
Investigator Signature:

19 Apr 07  
Date:

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Page 1 of 1

**INVESTIGATOR: (B17181)**

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313 East Anderson Lane #200  
Austin, TX 78752

PROTOCOL 6270-229

INVESTIGATOR NO.: 5

RANDOMIZATION NUMBER: R5004

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: 15:29 DATE: 15-Apr-2007

DATE RECEIVED IN LABORATORY: 16-Apr-2007

DATE REPORTED BY LABORATORY: 18-Apr-2007

SEX: F BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5018

Is this Clinically  
Significant/ Adverse  
Event?

Yes


No

**FIBRINOGEN**

Fibrinogen

257

200-400 mg/dL

  
Investigator Signature:

19 Apr 07  
Date:

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B17181

(INV)

**Covance CLS**

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

**LABORATORY REPORT**

ACCESSION NO. 0062482

Page 1 of 1

INVESTIGATOR: (B17181)

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c/o Marianna Alesi  
Covance-Austin  
313 East Anderson Lane #200  
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RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

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SCREENING NUMBER: S5018

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Significant/ Adverse  
Event?

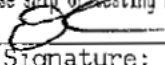
Yes

No

OXIDIZED LDL - See Note #1

OxidizeLDL Awaiting specimen arrival

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

  
Investigator Signature:

u Jun 07  
Date:

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

Testing performed by: Pacific Biometrics  
220 West Harrison Street; Seattle, WA 98119

B17181

(INV)

LOCATION: Covance CLS

RX TIME 04/17 '07 00:03

**Covance CLS**

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

**LABORATORY REPORT**

ACCESSION NO. 0062482

Page 1 of 1

## INVESTIGATOR: (B17181)

David Carter, M.D.  
c/o Marianna Alesi  
Covance-Austin  
313 East Anderson Lane #200  
Austin, TX 78752

## 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.: 5

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 15:29 DATE: 15-Apr-2007

DATE RECEIVED IN LABORATORY: 16-Apr-2007

DATE REPORTED BY LABORATORY: 16-Apr-2007

SEX: F BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5018

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:

11 Jun 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

B17181

(INV)

**Covance CLS**

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

ACCESSION NO. 0062482

Page 1 of 1

**INVESTIGATOR: (B17181)**

David Carter, M.D.  
c/o Marianna Alesi  
Covance-Austin  
313 East Anderson Lane #200  
Austin, TX 78752

PROTOCOL 6270-229

INVESTIGATOR NO.: 5

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 2

**SPONSOR REPORT TO:**

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

Week 0

COLLECTION TIME: 15:29 DATE: 15-Apr-2007

DATE RECEIVED IN LABORATORY: 16-Apr-2007

DATE REPORTED BY LABORATORY: 16-Apr-2007

SEX: F BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5018

Is this Clinically  
Significant/ Adverse  
Event?

Yes

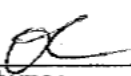
No

TOTAL IRON - See Note #1

C-REACTIVE PROTEIN - See Note #1

CARBOXYHEMOGLOBIN - See Note #1

Note #1 - No specimen received

  
Investigator Signature:

11 Jun 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

B17181

(INV)

**Covance CLS**

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

ACCESSION NO. 0062482

Page 1 of 1

INVESTIGATOR: (B17181)

David Carter, M.D.

c/o Marianna Alesi

Covance-Austin

313 East Anderson Lane #200

Austin, TX 78752

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.: 5

RANDOMIZATION NUMBER: R5004

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 15:29 DATE: 15-Apr-2007

DATE RECEIVED IN LABORATORY: 16-Apr-2007

DATE REPORTED BY LABORATORY: 19-Apr-2007

SEX: F BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5018

Is this Clinically  
Significant/ Adverse  
Event?

Yes


No

C-REACTIVE PROTEIN

CRP-HS

0.086

&lt;=0.287 mg/dL

  
Investigator Signature:19 Apr-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

B17181

(INV)

**Covance CLS**

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

ACCESSION NO. 0062482

Page 1 of 1

## INVESTIGATOR: (B17181)

David Carter, M.D.  
c/o Marianna Alesi  
Covance-Austin  
313 East Anderson Lane #200  
Austin, TX 78752

PROTOCOL 6270-229  
INVESTIGATOR NO.: 5  
RANDOMIZATION NUMBER: R5004  
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: 15:29 DATE: 15-Apr-2007  
DATE RECEIVED IN LABORATORY: 16-Apr-2007  
DATE REPORTED BY LABORATORY: 20-Apr-2007  
SEX: F BIRTHDATE: (b) (6) AGE: 36  
SCREENING NUMBER: S5018

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

## CARBOXYHEMOGLOBIN

Carboxyhem 9.6

% saturation  
No Ref Rng

VB

*Sandra Bardolmeasa/FAP*  
Investigator Signature:

11 Jun 07

*04/23/07*  
Date:

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

B17181

(INV)

**Covance CLS**

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**LABORATORY REPORT**

ACCESSION NO. 0062482

Page 1 of 1

## INVESTIGATOR: (B17181)

David Carter, M.D.  
c/o Marianna Alesi  
Covance-Austin  
313 East Anderson Lane #200  
Austin, TX 78752

PROTOCOL 6270-229

INVESTIGATOR NO.: 5

RANDOMIZATION NUMBER: R5004

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: 15:29 DATE: 15-Apr-2007

DATE RECEIVED IN LABORATORY: 16-Apr-2007

DATE REPORTED BY LABORATORY: 21-Apr-2007

SEX: F BIRTHDATE: (b) (6) AGE: 35

SCREENING NUMBER: S5018

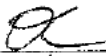
Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

## TOTAL IRON

Total Iron 52 30-160 ug/dL

  
Investigator Signature:

28 Apr 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

B17181

(INV)



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

ACCESSION NO. 0062482

Page 1 of 1

## INVESTIGATOR: (B17181)

David Carter, M.D.  
c/o Marianna Alesi  
Covance-Austin  
313 East Anderson Lane #200  
Austin, TX 78752

## 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.: 5

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 15:29 DATE: 15-Apr-2007

DATE RECEIVED IN LABORATORY: 16-Apr-2007

DATE REPORTED BY LABORATORY: 17-Apr-2007

SEX: F BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5018

Is this Clinically  
Significant/ Adverse  
Event?


Yes

No

URINE CREATININE, SPOT

Rnd Ur Crt 66

mg/dL No Ref Rng

  
Investigator Signature:

18 Apr 07  
Date:

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B17181

(INV)

**Covance CLS**

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Tel. +1 (800) 327 7270

**LABORATORY REPORT**

ACCESSION NO. 0062502

Page 1 of 1

## INVESTIGATOR: (B17181)

David Carter, M.D.  
c/o Marianna Alesi  
Covance-Austin  
313 East Anderson Lane #200  
Austin, TX 78752

## 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.: 5

RANDOMIZATION NUMBER: R5004

PATIENT INITIALS: (b) (6)

VISIT: 4

Week 2

COLLECTION TIME: 09:03 DATE: 30-Apr-2007

DATE RECEIVED IN LABORATORY: 01-May-2007

DATE REPORTED BY LABORATORY: 03-May-2007

SEX: F BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5018

Is this Clinically  
Significant/ Adverse  
Event?

Yes


No

## CARBOXYHEMOGLOBIN

Carboxyhem 3.3

% saturation

No Ref Rng

  
Investigator Signature:

04 May 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

817181

(INV)

**Covance CLS**

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

**LABORATORY REPORT**

ACCESSION NO. P150649

Page 1 of 1

## INVESTIGATOR: (B17181)

David Carter, M.D.  
c/o Marianna Alesi  
Covance-Austin  
313 East Anderson Lane #200  
Austin, TX 78752

## 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.: 5  
RANDOMIZATION NUMBER: R5004  
PATIENT INITIALS: (b) (6)  
VISIT: 24 HR UR

24 Hr Urine Collection  
COLLECTION TIME: 14:58 DATE: 10-Jul-2007  
DATE RECEIVED IN LABORATORY: 11-Jul-2007  
DATE REPORTED BY LABORATORY: 14-Jul-2007  
SEX: F BIRTHDATE: (b) (6) AGE: 36  
SCREENING NUMBER: S5018

Is this Clinically  
Significant/ Adverse  
Event?

Yes No

## URINE CREATININE, 24 HR

U24h Creat	956	600-1600 mg/24hr
UAlq24Crea	83.1	mg/dL No Ref Rng

## ELAPSED DATE AND TIME, 24HR

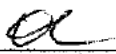
Elpsd D&T	1440	min
-----------	------	-----

## 24 HR COLLECTION INFORMATION

Start Date	09-Jul-2007
Start Time	14:58
Stop Date	10-Jul-2007
Stop Time	14:58

## TOTAL 24HR URINE VOLUME

Total Vol.	1151	mL
------------	------	----

  
Investigator Signature:

17 Jul 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

B17181

(INV)

**Covance CLS**

Marietta Henry, M.D., Director  
8211 SciCor Drive - Indianapolis, IN 46214-2985  
Tel. +1 (800) 327.7270

**LABORATORY REPORT**

ACCESSION NO. 0850695

Page 1 of 1

## INVESTIGATOR: (B17181)

David Carter, M.D.  
c/o Marianna Alesi  
Covance-Austin  
313 East Anderson Lane #200  
Austin, TX 78752

PROTOCOL 6270-229  
INVESTIGATOR NO.: 5  
RANDOMIZATION NUMBER: R5004  
PATIENT INITIALS: (b) (6)  
VISIT: 9

## SPONSOR REPORT TO:

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

Week 12

COLLECTION TIME: 07:13 DATE: 10-Jul-2007  
DATE RECEIVED IN LABORATORY: 11-Jul-2007  
DATE REPORTED BY LABORATORY: 13-Jul-2007  
SEX: F BIRTHDATE: (b) (6) AGE: 36  
SCREENING NUMBER: S5018

Is this Clinically  
Significant/ Adverse  
Event?

Yes No

## TOTAL IRON

Total Iron 26 L 30-160 ug/dL

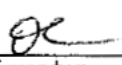
[ ] [X]

## C-REACTIVE PROTEIN

CRP-HS 0.052 <=0.287 mg/dL

## CARBOXYHEMOGLOBIN

Carboxyhem 3.1 % saturation  
No Ref Rng

  
Investigator Signature:

17 Jul 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

B17181

(INV)

**Covance CLS**

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

**LABORATORY REPORT**

ACCESSION NO. 0850695

Page 1 of 3

**INVESTIGATOR: (B17181)**

David Carter, M.D.  
c/o Marianna Alesi  
Covance-Austin  
313 East Anderson Lane #200  
Austin, TX 78752

**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.: 5

RANDOMIZATION NUMBER: R5004

PATIENT INITIALS: (b) (6)

VISIT: 9

Week 12

COLLECTION TIME: 07:13 DATE: 10-Jul-2007

DATE RECEIVED IN LABORATORY: 11-Jul-2007

DATE REPORTED BY LABORATORY: 12-Jul-2007

SEX: F BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5018

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

**CHEMISTRY PANEL**

Total Bili	0.2		0.2-1.2 mg/dL
Alk Phos	111	H	31-106 U/L
ALT (SGPT)	13		6-34 U/L
AST (SGOT)	15		9-34 U/L
GGT	27		4-49 U/L
LDH	137		53-234 U/L
Urea Nitr	13		4-24 mg/dL
Creatinine	1.0		0.4-1.1 mg/dL
Glucose	103		70-115 mg/dL
Uric Acid	3.3		2.1-7.2 mg/dL
Calcium	9.9		8.3-10.6 mg/dL
Phosphorus	4.9		2.2-5.1 mg/dL
Total Prot	7.2		6.1-8.4 g/dL
Albumin	4.1		3.3-4.9 g/dL
Sodium	142		132-147 mEq/L
Potassium	3.8		3.4-5.4 mEq/L
Chloride	105		94-112 mEq/L

[ ]

[✓]

Investigator Signature:

17 Jul 07  
Date:

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B17181

(INV)

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**LABORATORY REPORT**

ACCESSION NO. 0850695

Page 2 of 3

INVESTIGATOR: (B17181)

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313 East Anderson Lane #200  
Austin, TX 78752

PROTOCOL 6270-229  
INVESTIGATOR NO.: 5  
RANDOMIZATION NUMBER: R5004  
PATIENT INITIALS: (b) (6)  
VISIT: 9

SPONSOR REPORT TO:

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

Week 12

COLLECTION TIME: 07:13 DATE: 10-Jul-2007

DATE RECEIVED IN LABORATORY: 11-Jul-2007

DATE REPORTED BY LABORATORY: 12-Jul-2007

SEX: F BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5018

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

**HEMATOLOGY & DIFFERENTIAL PANEL**

HGB	12.5	11.6-16.4 g/dL
HCT	42	34-48 %
RBC	4.3	4.1-5.6x10 <sup>6</sup> /uL
MCV	98	79-98 fL
MCH	29	26-34 pg
MCHC	30 L	31-38 g/dL
RDW	14.6	12.0-15.0 %
RBC Morph	Normocytic	
WBC	8.87	3.80-10.70 x10 <sup>3</sup> /uL
Neutrophil	5.41	1.96-7.23 x10 <sup>3</sup> /uL
Lymphocyte	2.53	0.91-4.28 x10 <sup>3</sup> /uL
Monocytes	0.78	0.12-0.92 x10 <sup>3</sup> /uL
Eosinophil	0.11	0.00-0.57 x10 <sup>3</sup> /uL
Basophils	0.03	0.00-0.20 x10 <sup>3</sup> /uL
Neutrophil	61.0	40.5-75.0 %
Lymphocyte	28.5	15.4-48.5 %
Monocytes	8.8	2.6-10.1 %
Eosinophil	1.2	0.0-6.8 %
Basophils	0.4	0.0-2.0 %
Platelets	219	140-400 x10 <sup>3</sup> /uL

[ ]

[✓]

Investigator Signature:

17 Jul 07  
Date:

H(High) or L(Low)-Values above or below Covance CLS reference range  
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B17181

(INV)

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

**LABORATORY REPORT**

ACCESSION NO. 0850695

Page 3 of 3

## INVESTIGATOR: (B17181)

David Carter, M.D.  
c/o Marianna Alesi  
Covance-Austin  
313 East Anderson Lane #200  
Austin, TX 78752

PROTOCOL 6270-229  
INVESTIGATOR NO.: 5  
RANDOMIZATION NUMBER: R5004  
PATIENT INITIALS: (b) (6)  
VISIT: 9

## SPONSOR REPORT TO:

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

Week 12

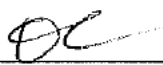
COLLECTION TIME: 07:13 DATE: 10-Jul-2007  
DATE RECEIVED IN LABORATORY: 11-Jul-2007  
DATE REPORTED BY LABORATORY: 12-Jul-2007  
SEX: F BIRTHDATE: (b) (6) AGE: 36  
SCREENING NUMBER: S5018

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	1.005	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-Trace
Nitrite	Negative	Ref Rng: Negative
Leuk Est	Negative	Ref Rng: Negative
Microscop	Negative	

  
Investigator Signature:

17 Jul 07  
Date:

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

B17181

(INV)

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

**LABORATORY REPORT**

ACCESSION NO. 0850695

Page 1 of 1

## INVESTIGATOR: (B17181)

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c/o Marianna Alesi  
Covance-Austin  
313 East Anderson Lane #200  
Austin, TX 78752

## 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.: 5

RANDOMIZATION NUMBER: R5004

PATIENT INITIALS: (b) (6)

VISIT: 9

Week 12

COLLECTION TIME: 07:13 DATE: 10-Jul-2007

DATE RECEIVED IN LABORATORY: 11-Jul-2007

DATE REPORTED BY LABORATORY: 12-Jul-2007

SEX: F BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5018

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No


## HOMOCYSTEINE

\*1 HCY

9.44

3.36-20.44 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.

  
Investigator Signature:

17 Jul 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

B17181

(INV)



**Covance CLS**

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

---

LABORATORY REPORT

ACCESSION NO. 0850695

Page 1 of 1

## INVESTIGATOR: (B17181)

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313 East Anderson Lane #200  
Austin, TX 78752

PROTOCOL 6270-229  
INVESTIGATOR NO.: 5  
RANDOMIZATION NUMBER: R5004  
PATIENT INITIALS: (b) (6)  
VISIT: 9

## SPONSOR REPORT TO:

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

Week 12

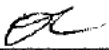
COLLECTION TIME: 07:13 DATE: 10-Jul-2007  
DATE RECEIVED IN LABORATORY: 11-Jul-2007  
DATE REPORTED BY LABORATORY: 12-Jul-2007  
SEX: F BIRTHDATE: (b) (6) AGE: 36  
SCREENING NUMBER: S5018

Is this Clinically  
Significant/ Adverse  
Event?

Yes No

## FIBRINOGEN

Fibrinogen 311 200-400 mg/dL

  
Investigator Signature:

17 Jul 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

B17181

(INV)

**Covance CLS**

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

**LABORATORY REPORT**

ACCESSION NO. 0850695

Page 1 of 1

## INVESTIGATOR: (B17181)

David Carter, M.D.  
c/o Marianna Alesi  
Covance-Austin  
313 East Anderson Lane #200  
Austin, TX 78752

## 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.: 5

RANDOMIZATION NUMBER: R5004

PATIENT INITIALS: (b) (6)

VISIT: 9

Week 12

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SCREENING NUMBER: S5018

Is this Clinically  
Significant/ Adverse  
Event?

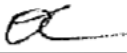
Yes

No

URINE CREATININE, SPOT

Rnd Ur Crt 16

mg/dL No Ref Rng

  
Investigator Signature:

17 Jul 07  
Date:

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SEX: F BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5018


Is this Clinically  
Significant/ Adverse  
Event?

Yes No

sICAM-1

sICAM-1

To follow

  
Investigator Signature:

17 Jul 07  
Date:

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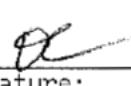
Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

RBC CELL WASHING (4-ABP-HB)

Wash/Store Completed

  
Investigator Signature:

17 Jul 07  
Date:

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PROTOCOL 6270-229  
INVESTIGATOR NO.: 5  
RANDOMIZATION NUMBER: R5004  
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VISIT: 9

Week 12


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DATE REPORTED BY LABORATORY: 12-Jul-2007  
SEX: F BIRTHDATE: (b) (6) AGE: 36  
SCREENING NUMBER: S5018

Is this Clinically  
Significant/ Adverse  
Event?

Yes No

HAS PATIENT FASTED 8 HOURS?

Fasted? Yes

  
Investigator Signature:

17 Jul 07  
Date:

B17181

(INV)

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VISIT: 9

Week 12

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DATE REPORTED BY LABORATORY: 12-Jul-2007

SEX: F BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5018

Is this Clinically  
Significant/ Adverse  
Event?

Yes No

## HEMOGLOBIN A1C


Hgb A1c 5.8

Normals:

4.3-6.1%

Stable Diabetics:

4.2-11.2%

  
Investigator Signature:

17 Jul 07  
Date:

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PROTOCOL 6270-229  
INVESTIGATOR NO.: 5  
RANDOMIZATION NUMBER: R5004  
PATIENT INITIALS: (b) (6)  
VISIT: 9

## SPONSOR REPORT TO:

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Week 12

COLLECTION TIME: 07:13 DATE: 10-Jul-2007  
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DATE REPORTED BY LABORATORY: 12-Jul-2007  
SEX: F BIRTHDATE: (b) (6) AGE: 36  
SCREENING NUMBER: S5018

Is this Clinically  
Significant/ Adverse  
Event?

Yes


No

## LIPID PANEL

Triglycer	127		39-176 mg/dL
Cholest	164		141-240 mg/dL
HDL Dex-S	31	L	34-82 mg/dL
LDL Chol	108		75-172 mg/dL

[ ]

[✓]

  
Investigator Signature:

17 Jul 07

Date:

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**SPONSOR REPORT TO:**

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PROTOCOL 6270-229

INVESTIGATOR NO.: 5

RANDOMIZATION NUMBER: R5004

PATIENT INITIALS: (b) (6)

VISIT: 9

Week 12

COLLECTION TIME: 07:13 DATE: 10-Jul-2007

DATE RECEIVED IN LABORATORY: 11-Jul-2007

DATE REPORTED BY LABORATORY: 12-Jul-2007

SEX: F BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5018

Is this Clinically  
Significant/ Adverse  
Event?


Yes

No

OXIDIZED LDL

OxidizeLDL

To follow

  
Investigator Signature:

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

B17181

(INV)

LOCATION: Covance CLS

Covance CLS RX TIME 07/13 '07 01:09



**Covance CLS**

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Austin, TX 78752

PROTOCOL 6270-229

INVESTIGATOR NO.: 5

RANDOMIZATION NUMBER: R5004

PATIENT INITIALS: (b) (6)

VISIT: 9

## SPONSOR REPORT TO:

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Madison, WI United States 53704

Week 12

COLLECTION TIME: 07:13 DATE: 10-Jul-2007

DATE RECEIVED IN LABORATORY: 11-Jul-2007

DATE REPORTED BY LABORATORY: 26-Jul-2007

SEX: F BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5018

Is this Clinically  
Significant/ Adverse  
Event?

Yes

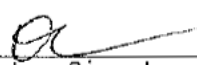
No

sICAM-1

sICAM-1 530 H 115-306 ng/mL

[ ]

[x]

  
Investigator Signature:

09 Aug 07  
Date:

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