

CRF Report for Study E6270229

Report run by Melissa Zeis at 12-12-2007 15:58:29

Report on Selected Data

Filter: Site CDB_001, Patient 3026

Legend: How different values appear in the report

| | |
|-----------------------------|----------------|
| Prompt | Abc 123 |
| Data value | Abc 123 |
| Data value with discrepancy | Abc 123 |

All time stamps displayed in this report are in the timezone of the database server.

The data contained in this report is current at the time of printing (time as shown above)

Page ID: D11966713

/ Covance No. 6270-229

Data Clarification Form

To: Covance CRU Daytona Beach

Investigator: Frank Farmer

Date: 15-APR-2008

Patient#: 3026

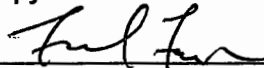
Patient Initials:

Reviewer: Dawn Taylor

| Form Name / Visit Name | Page # Date | Questions/Comments | Resolution |
|--------------------------------------------------------------------------------------------|----------------------------|-------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------|
| Previous and Concomitant Medications PRECON_MEDS Disc ID: 1385356713 Type: MANUAL | 26 03MAY07 Closed: N | Please confirm that 'TAB', currently presented as the specify for Route is best presented as the Dose Unit. | <input checked="" type="checkbox"/> Dose/Dose Unit=1 TAB Specify=null <input type="checkbox"/> Other: _____ |

verified
to file
some
04/27/08

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


Authorized Personnel Signature

16 APR 2008
Date

Page ID: D11966713

/ Covance No. 6270-229

Data Clarification Form

To: Covance CRU Daytona Beach

Investigator: Frank Farmer

Date: 15-APR-2008

Patient#: 3026

Patient Initials:

Reviewer: Dawn Taylor

| Form Name / Visit Name | Page # Date | Questions/Comments | Resolution |
|-----------------------------------------------------------------------------------------------|----------------------------|----------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------|
| Previous and Concomitant Medications PRECON_MEDS Disc ID: 1385356713 Type: MANUAL | 26 03MAY07 Closed: N | Please confirm that 'TAB', currently presented as the specify for Route is best presented as the Dose Unit. | <input checked="" type="checkbox"/> Dose/Dose Unit=1 TAB Specify=null <input type="checkbox"/> Other: _____ |

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


Authorized Personnel Signature

16 APR 2008
Date

See Case

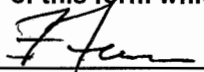
Data Clarification Form

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

Patient#: 3026
Patient Initials:
Reviewer: Dawn Taylor

| Form Name / Visit Name | Page # Date | Questions/Comments | Resolution |
|-----------------------------------------------------------------------------|----------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Medical History SCREENING Disc ID: 1289698013 Type: MANUAL | 3 03MAY07 Closed: N | A previous medication of 'Aleve' is currently noted for indication 'Headache'. Start date of medication is 1977, Stop date is 2007. Please verify if a MedHx finding should be presented. | <input checked="" type="checkbox"/> Add MedHx System: <u>Neurological</u> Finding: <u>Headache</u> Onset date: <u>unk-unk-1977</u> Resolved date: <u>unk-unk-07 DEC 2007</u> Indicator question=Yes <input type="checkbox"/> No MedHx <input type="checkbox"/> Delete med, usage stop prior to study entry |
| Study Completion STUDY_COMP Disc ID: 1236356513 Type: MULTIVARIATE | 35 24MAY07 Closed: N | Specific reason is provided, but primary reason subject did not complete study product is <Consent Withdrawn>, for which 'specify' is not an option. Please reconcile. | <input checked="" type="checkbox"/> Delete comment/specify <input type="checkbox"/> Other: _____ |

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


Authorized Personnel Signature

23 JAN 2008
Date

CRF Report for Study E6270229



Patient: 3026

CRF: Header_Page

Visit: SCREENING

Entered By: Christina Breedlove

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? N

Visit Date: 03-05-2007

Entry Time: 26-07-2007 09:26:23

Modification Time: 26-07-2007 09:26:50

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 1

Document #: R150397313

CRF Status: Entry Complete

Approver:

Verifier:

Section: Header_Info

Blank? N

Section Status: Entry Complete

Visit: SCREENING

Section Date: 03-05-2007

Entered By: Christina Breedlove

Entry Time: 26-07-2007 09:26:23

Last Modification Time: 26-07-2007 09:26:50

Page number: 1

RDC CASE REPORT FORM

SMOKER

Sponsor Name

Investigator

Site

RJ REYNOLDS TOBACCO COMPANY

DR FARMER

3

SWITCHING FROM USUAL BRAND CIGARETTES TO A TOBACCO-HEATING CIGARETTE OR SNUS

-A MULTI-CENTER EVALUATION OF HEALTH-RELATED QUALITY OF LIFE ASSESSMENTS AND BIOMARKERS

OF EXPOSURE AND HARM

CRF Report for Study E6270229



Patient: 3026
 CRF: Screening
 Visit: SCREENING
 Entered By: Christina Breedlove
 Discrepancies: Closed
 Approval Status: Not Approved
 Verification: Not Verified
 Comment:

Site: CDB_001
 Blank? N
 Visit Date: 03-05-2007
 Entry Time: 26-07-2007 09:26:51
 Modification Time: 10-12-2007 09:44:40
 Approval Time:
 Verification Time:

Investigator: CDB_001
 CRF Page #: 2
 Document #: R150397513
 CRF Status: Entry Complete

Approver:
 Verifier:

| | | | |
|---------------------------------|---------|---------------------------------------------|--------------------------------|
| Section: Inc_Criteria | 1 of 10 | Blank? N | Section Status: Entry Complete |
| Visit: SCREENING | | Section Date: 03-05-2007 | |
| Entered By: Christina Breedlove | | Entry Time: 26-07-2007 09:26:51 | |
| | | Last Modification Time: 26-07-2007 10:01:53 | |
| | | 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: 03-05-2007 | |
| Entered By: Christina Breedlove | | Entry Time: 26-07-2007 09:26:51 | |
| | | Last Modification Time: 07-12-2007 18:30:19 | |
| | | Page number: 20 | |

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

CRF Report for Study E6270229



Patient: 3026

CRF: Screening

Visit: SCREENING

Site: CDB_001

Blank? N

Visit Date: 03-05-2007

Investigator: CDB_001

CRF Page #: 2

Document #: R150397513

| 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: | 03-05-2007 | | |
| Entered By: | Christina Breedlove | | Entry Time: | 26-07-2007 09:26:51 | | |
| | | | Last Modification Time: | 26-07-2007 10:01:53 | | |
| | | | Page number: | 3 | | |
| Exclusion Criteria | | | | | | |
| Sequence number | | | | | | Yes/No |
| 01 | For Groups A, B, and C, regular use of any other tobacco or nicotine-containing product or device other than tobacco burning cigarettes from 6 months prior to the study through Week 24, including cigars, pipes, chewing tobacco, snuff, snus, nicotine patch, nicotine gum, etc. | | | | | NO |
| 02 | History or clinical manifestations of significant metabolic, hepatic, renal, hematological, pulmonary, cardiovascular, gastrointestinal, urological, neurological, or psychiatric disorders. | | | | | NO |
| 03 | History of hypersensitivity or allergies to any drug compound unless approved by the Investigator(s). | | | | | NO |
| 04 | History or presence of an abnormal ECG, which, in the Investsigator(s)' opinion, is clinically significant. | | | | | NO |
| 05 | History of alcoholism of drug addiction within 1 year prior to Study Entry; excessive alcohol consumption will be discouraged. | | | | | NO |
| 06 | Poor peripheral venous access. | | | | | NO |
| 07 | Donation of blood from 30 days prior to Screening through Week 24 (or Study Completion), inclusive, or of plasma from 2 weeks prior to Screening through Week 24 (or Study Completion), inclusive. | | | | | NO |
| 08 | Receipt of blood products within 2 months prior to Study Entry. | | | | | NO |
| 09 | Evidence of visible oral cancer, as found in an oral health examination or based on oral health questions at each visit. | | | | | NO |
| 10 | Any acute or chronic condition that, in the Investigator(s)' opinion, would limit the subject's ability to complete and/or participate in this clinical study. | | | | | NO |
| 11 | Subject or a relative of the subject is or has ever been employed by the tobacco industry. | | | | | NO |
| 12 | Subject is an employee of Covance. | | | | | NO |
| 13 | Subject has participated in any other investigational study drug or product trial in which receipt of an investigational study drug or product occurred within 30 days prior to Check-in (inclusive). | | | | | NO |

CRF Report for Study E627022C



Patient: 3026

CRF: Screening

Visit: SCREENING

Site: CDB_001

Blank? N

Visit Date: 03-05-2007

Investigator: CDB_001

CRF Page #: 2

Document #: R150397513

| | | | | |
|---------------------------------------------------------------------|---------|----------|---------------------------------------------|--------------------------------|
| Section: Informed_Consent | 4 of 10 | Blank? N | Section Date: 03-05-2007 | Section Status: Entry Complete |
| Visit: SCREENING | | | Entry Time: 26-07-2007 09:26:51 | |
| Entered By: Christina Breedlove | | | Last Modification Time: 26-07-2007 10:01:53 | |
| | | | Page number: 4 | |
| Informed Consent | | | | |
| Date the Subject Signed the Smoker Informed Consent Form 03-05-2007 | | | | |

| | | | | |
|-----------------------------------------------------|----------|-----------|---------------------------------------------|--------------------------------|
| Section: Elig | 5 of 10 | Blank? N | Section Date: 03-05-2007 | Section Status: Entry Complete |
| Visit: SCREENING | | | Entry Time: 26-07-2007 09:26:51 | |
| Entered By: Christina Breedlove | | | Last Modification Time: 26-07-2007 10:01:53 | |
| | | | Page number: 4 | |
| Subject Eligibility | | | | |
| Did the subject meet all of the inclusion criteria? | | YES | | |
| Did the subject have any of the exclusion criteria? | | NO | | |
| Criteria | Criteria | | | |
| Type | Number | Deviation | Date Exemption | Granted |

| | | | | |
|------------------------------------------------------------------------------------------------------------|---------|----------|---------------------------------------------|--------------------------------|
| Section: Patient_Rep_Outc | 6 of 10 | Blank? N | Section Date: 03-05-2007 | Section Status: Entry Complete |
| Visit: SCREENING | | | Entry Time: 26-07-2007 09:26:51 | |
| Entered By: Christina Breedlove | | | Last Modification Time: 26-07-2007 10:01:53 | |
| | | | Page number: 4 | |
| Patient Reported Outcome (PRO) Questionnaires | | | | |
| Did the subject complete the Smoker Screening Questionnaire prior to any study procedures being performed? | | | | Yes / No YES |

| | | | | |
|---------------------------------|---------|------------------|---------------------------------------------|--------------------------------|
| Section: Demog | 7 of 10 | Blank? N | Section Date: 03-05-2007 | Section Status: Entry Complete |
| Visit: SCREENING | | | Entry Time: 26-07-2007 09:26:51 | |
| Entered By: Christina Breedlove | | | Last Modification Time: 07-12-2007 18:30:40 | |
| | | | Page number: 5 | |
| Demographics | | Subject Initials | | |
| Date of Birth | Gender | Height | Height Unit | Weight |
| (b) (6) | F | 163.6 | CM | 084.2 |
| | | xxx.x | | xxx.x |
| Ethnicity | | | | Weight Unit KG |

CRF Report for Study E6270229

Patient: 3026
CRF: Screening
Visit: SCREENING

Site: CDB_001
Blank? N
Visit Date: 03-05-2007

Investigator: CDB_001
CRF Page #: 2
Document #: R150397513

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

| | | | | | | | |
|---------------------------------|----------------|---------------------------------------------|-------|---------------------------------|------------------|--------------------------------|--|
| Section: Vital | | 8 of 10 | | Blank? N | | Section Status: Entry Complete | |
| Visit: SCREENING | | Section Date: 03-05-2007 | | Entry Time: 26-07-2007 09:26:51 | | | |
| Entered By: Christina Breedlove | | Last Modification Time: 26-07-2007 10:01:53 | | Page number: 5 | | | |
| VITAL SIGNS | | | | | | | |
| Actual Time | Blood Pressure | | Pulse | Respiratory Rate | Oral Temperature | Unit | |
| 0953 | Systolic | Diastolic | 069 | 14 | 036.6 | C | |
| | 117 | 079 | | | xxx.x | | |
| Comments | | | | | | | |

| | | | | | | | |
|---------------------------------------|-----------------|---------------------------------------------|--|---------------------------------|--|--------------------------------|--|
| Section: Hdyf_Oral_Health | | 9 of 10 | | Blank? N | | Section Status: Entry Complete | |
| Visit: SCREENING | | Section Date: 03-05-2007 | | Entry Time: 26-07-2007 09:26:51 | | | |
| Entered By: Christina Breedlove | | Last Modification Time: 07-12-2007 18:31:24 | | Page number: 5 | | | |
| HDYF? / ORAL HEALTH QUESTIONS INQUIRY | | | | | | | |
| | | Oral Health Questions | | Performed? | | Comments | |
| Actual Time | HDYF Performed? | | | YES | | | |
| NR | YES | | | | | | |

| | | | | | | | |
|-------------------------------------------------|-----------|---------------------------------------------|--------|---------------------------------|--|--------------------------------|--|
| Section: Lab_Eval | | 10 of 10 | | Blank? N | | Section Status: Entry Complete | |
| Visit: SCREENING | | Section Date: 03-05-2007 | | Entry Time: 26-07-2007 09:26:51 | | | |
| Entered By: Christina Breedlove | | Last Modification Time: 26-07-2007 11:26:28 | | Page number: 6 | | | |
| Laboratory Evaluations | | | | | | | |
| Were the scheduled laboratory samples obtained? | | YES | | No, specify | | | |
| Requisition Number 1 | | N746086 | | | | | |
| Requisition Number 2 (if applicable) | | | | | | | |
| Were there any clinically significant labs? | | NO | | (Yes, specify below) | | | |
| Requisition Number | Test Name | H/L | Lab ID | Lab Name | | | |

CRF Report for Study E6270229



Patient: 3026
CRF: Screening2
Visit: SCREENING
Entered By: Christina Breedlove
Discrepancies: Closed
Approval Status: Not Approved
Verification: Not Verified
Comment:

Site: CDB_001
Blank? N
Visit Date: 03-05-2007
Entry Time: 26-07-2007 10:01:54
Modification Time: 11-12-2007 09:46:42
Approval Time:
Verification Time:

Investigator: CDB_001
CRF Page #: 3
Document #: R150411613
CRF Status: Entry Complete

Approver:
Verifier:

| | | | |
|---------------------------------|---------|---------------------------------------------|--------------------------------|
| Section: Preg_Test | 1 of 10 | Blank? N | Section Status: Entry Complete |
| Visit: SCREENING | | Section Date: 03-05-2007 | |
| Entered By: Christina Breedlove | | Entry Time: 26-07-2007 10:01:54 | |
| | | Last Modification Time: 26-07-2007 11:25:01 | |
| | | Page number: 6 | |
| Urine Pregnancy Test | | | |
| Result | | | |
| NEGA | | | |
| TIVE | | | |

| | | | |
|---------------------------------|---------|---------------------------------------------|--------------------------------|
| Section: Urine_Drug | 2 of 10 | Blank? N | Section Status: Entry Complete |
| Visit: SCREENING | | Section Date: 03-05-2007 | |
| Entered By: Christina Breedlove | | Entry Time: 26-07-2007 10:01:54 | |
| | | Last Modification Time: 26-07-2007 11:25:01 | |
| | | 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: 03-05-2007 | |
| Entered By: Christina Breedlove | | Entry Time: 26-07-2007 10:01:54 | |
| | | Last Modification Time: 26-07-2007 11:25:01 | |
| | | 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: 03-05-2007 | |
| Entered By: Christina Breedlove | | Entry Time: 26-07-2007 10:01:54 | |
| | | Last Modification Time: 10-12-2007 17:39:51 | |
| | | Page number: 7 | |

CRF Report for Study E6270229



Patient: 3026
CRF: Screening2
Visit: SCREENING

Site: CDB_001
Blank? N
Visit Date: 03-05-2007

Investigator: CDB_001
CRF Page #: 3
Document #: R150411613

Section: Med_Hx 4 of 10

Medical History

Does the subject have any relevant medical history? NO

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

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

Section: ECG 5 of 10

Blank? N

Section Status: Entry Complete

Visit: SCREENING

Section Date: 03-05-2007

Entered By: Christina Breedlove

Entry Time: 26-07-2007 10:01:54

Last Modification Time: 26-07-2007 11:25:01

Page number: 8

12-LEAD ELECTROCARDIOGRAM REPORT

Actual Time 0958 Ventricular Heart Rate 67

Cardiac Cycle Measurements

| PR Interval | QRS Duration | QT Interval | QTc Interval |
|-------------|--------------|-------------|--------------|
| 162 | 74 | 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: 03-05-2007

Entered By: Christina Breedlove

Entry Time: 26-07-2007 10:01:54

Last Modification Time: 26-07-2007 11:25:01

CRF Report for Study E6270229

Patient: 3026
CRF: Screening2
Visit: SCREENING

Site: CDB_001
Blank? N
Visit Date: 03-05-2007

Investigator: CDB_001
CRF Page #: 3
Document #: R150411613

| | | | | | |
|--------------------------|--|----------------------------|--|-----------------------------------------------------|--|
| Section: Usual_Brand_Cig | | 6 of 10 | | Page number: 9 | |
| Usual Brand | | USUAL BRAND CIGARETTE PACK | | DATA | |
| MARLBORO | | Type | | Length | |
| | | NON-MENTHOL | | LONG 90-105MM | |
| Style | | Pack | | How long have these been the subject's usual brand? | |
| LIGHTS/LOW TAR | | HARD | | UNK months | |
| | | | | 15 years | |

| | | | | | | | |
|---------------------------------|--|---------------------------------------------|--|----------|--|--------------------------------|--|
| Section: Ftc_Tar_Level | | 7 of 10 | | Blank? N | | Section Status: Entry Complete | |
| Visit: SCREENING | | Section Date: 03-05-2007 | | | | | |
| Entered By: Christina Breedlove | | Entry Time: 26-07-2007 10:01:54 | | | | | |
| | | Last Modification Time: 26-07-2007 11:25:01 | | | | | |
| | | Page number: 9 | | | | | |
| FTC TAR LEVEL OF USUAL BRAND | | | | | | | |
| FTC Tar Level (mg) | | | | | | | |
| 10.4 | | | | | | | |

| | | | | | | | |
|---------------------------------|--|---------------------------------------------|--|----------|--|--------------------------------|--|
| Section: Expired_Carbon_M | | 8 of 10 | | Blank? N | | Section Status: Entry Complete | |
| Visit: SCREENING | | Section Date: 03-05-2007 | | | | | |
| Entered By: Christina Breedlove | | Entry Time: 26-07-2007 10:01:54 | | | | | |
| | | Last Modification Time: 26-07-2007 11:25:01 | | | | | |
| | | Page number: 10 | | | | | |
| EXPIRED CARBON MONOXIDE | | | | | | | |
| Actual Time | | ECO Level (ppm) | | %COHb | | Comments | |
| 0930 | | 19 | | 03.6 | | | |

| | | | | | | | |
|--------------------------------------|--|---------------------------------------------|--|---------------|--|--------------------------------|--|
| Section: Best_Baseline_Sp | | 9 of 10 | | Blank? N | | Section Status: Entry Complete | |
| Visit: SCREENING | | Section Date: 03-05-2007 | | | | | |
| Entered By: Christina Breedlove | | Entry Time: 26-07-2007 10:01:54 | | | | | |
| | | Last Modification Time: 09-12-2007 13:07:15 | | | | | |
| | | Page number: 10 | | | | | |
| BEST BASELINE SPIROMETRY TEST RESULT | | | | | | | |
| Actual Time | | FEV 1 Predicted | | FVC Predicted | | | |
| of FEV1/FVC Test | | Testing Position | | FEV1 L (%) | | FVC L (%) | |
| 1009 | | STANDING | | 2.73 93 | | 3.41 93 | |
| | | | | | | Comments | |

| | | | | | | | |
|---------------|--|-------|--|---|--|----------------|--|
| Irvs Training | | 10 10 | | N | | Entry Complete | |
|---------------|--|-------|--|---|--|----------------|--|

CRF Report for Study E6270229

Patient: 3026

CRF: Screening2

Visit: SCREENING

Site: CDB_001

Blank? N

Visit Date: 03-05-2007

Investigator: CDB_001

CRF Page #: 3

Document #: R150411613

Section: lrvs_Training

10 of 10

Blank?

Section Status:

Visit: SCREENING

Section Date: 03-05-2007

Entered By: Christina Breedlove

Entry Time: 26-07-2007 10:01:54

Last Modification Time: 26-07-2007 11:25:01

Page number: 10

IVRS TRAINING

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

YES

CRF Report for Study E6270229



Patient: 3026

CRF: Week-2

Visit: WEEK -2

Entered By: Christina Breedlove

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? N

Visit Date: 23-05-2007

Entry Time: 30-07-2007 10:55:44

Modification Time: 30-07-2007 10:57:18

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 4

Document #: R150960713

CRF Status: Entry Complete

Approver:

Verifier:

Section: Usual_Brand_Coll

Blank? N

Section Status: Entry Complete

Visit: WEEK -2

Section Date: 23-05-2007

Entered By: Christina Breedlove

Entry Time: 30-07-2007 10:55:44

Last Modification Time: 30-07-2007 10:57:18

Page number: 11

USUAL BRAND

CIGARETTE COLLECTION TRAINING

1. Did subject receive foam block?

YES

2. Did subject receive training on usual brand collection?

YES

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

YES

CRF Report for Study E6270229

Patient: 3026

CRF: Week 0 Baseline

Visit: WEEK 0 (BASELINE)

Entered By: Christina Breedlove

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? N

Visit Date: 23-05-2007

Entry Time: 30-07-2007 12:45:11

Modification Time: 07-12-2007 18:46:36

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 5

Document #: R150976213

CRF Status: Entry Complete

Approver:

Verifier:

| | | | |
|---------------------------------|----------------------------------------------------------|---------------------------------------------|--------------------------------|
| Section: Pro_Questionnaire | 1 of 11 | Blank? N | Section Status: Entry Complete |
| Visit: WEEK 0 (BASELINE) | | Section Date: 23-05-2007 | |
| Entered By: Christina Breedlove | | Entry Time: 30-07-2007 12:45:11 | |
| | | Last Modification Time: 30-07-2007 13:52:27 | |
| | | Page number: 12A | |
| PRO QUESTIONNAIRES | | | |
| Date | 1. With the possible exception of urinating, did subject | YES / NO | |
| 23-05-2007 | complete Smoker Routine Questionnaire PRIOR to any | | |
| | study procedures being performed? | YES | |

| | | | |
|---------------------------------|--------------------|---------------------------------------------|--------------------------------|
| Section: Urine_Drug | 2 of 11 | Blank? N | Section Status: Entry Complete |
| Visit: WEEK 0 (BASELINE) | | Section Date: 23-05-2007 | |
| Entered By: Christina Breedlove | | Entry Time: 30-07-2007 12:45:11 | |
| | | Last Modification Time: 30-07-2007 13:52:27 | |
| | | Page number: 12A | |
| Drug Screen | | | |
| Date | Drug Screen Result | | |
| 23-05-2007 | NEG | | |

| | | | |
|---------------------------------|---------------------|---------------------------------------------|--------------------------------|
| Section: Alcohol_Screen | 3 of 11 | Blank? N | Section Status: Entry Complete |
| Visit: WEEK 0 (BASELINE) | | Section Date: 23-05-2007 | |
| Entered By: Christina Breedlove | | Entry Time: 30-07-2007 12:45:11 | |
| | | Last Modification Time: 30-07-2007 13:52:27 | |
| | | Page number: 12A | |
| Alcohol Screen | | | |
| Date | Breathalyzer Result | | |
| 23-05-2007 | NEG | | |

| | | | |
|---------------------------------|---------|---------------------------------------------|--------------------------------|
| Section: Preg_Test | 4 of 11 | Blank? N | Section Status: Entry Complete |
| Visit: WEEK 0 (BASELINE) | | Section Date: 23-05-2007 | |
| Entered By: Christina Breedlove | | Entry Time: 30-07-2007 12:45:11 | |
| | | Last Modification Time: 30-07-2007 13:52:27 | |
| | | Page number: 12A | |

CRF Report for Study E6270229

Patient: 3026

CRF: Week 0 Baseline

Visit: WEEK 0 (BASELINE)

Site: CDB_001

Blank? N

Visit Date: 23-05-2007

Investigator: CDB_001

CRF Page #: 5

Document #: R150976213

| | | |
|--------------------|--------------|---------|
| Section: Preg_Test | | 4 of 11 |
| Pregnancy Test | | |
| Date | Result | |
| 23-05-2007 | NEGA TIVE | |

| | | | | | | |
|---------------------------------|------------|---------------------------------------------|------------|--------------------------------|--------------|----------|
| Section: Urine_Coll | | 5 of 11 | Blank? N | Section Status: Entry Complete | | |
| Visit: WEEK 0 (BASELINE) | | Section Date: 23-05-2007 | | | | |
| Entered By: Christina Breedlove | | Entry Time: 30-07-2007 12:45:11 | | | | |
| | | Last Modification Time: 07-12-2007 18:40:22 | | | | |
| | | Page number: 12A | | | | |
| 24-Hour Urine Collection | | | | | | |
| Scheduled Timepoint | Start Date | Start Time | Stop Date | Stop Time | Total Volume | Comments |
| SPOT URINE VOID | 23-05-2007 | 1721 | NA | NA | NA | |
| 0 HOUR TO 24 HOURS | 23-05-2007 | 1721 | 24-05-2007 | 1635 | 1450 | |

| | | | | | | |
|---------------------------------|-------------|---------------------------------------------|----------|--------------------------------|--|--|
| Section: Hdyf_Oral_Health | | 6 of 11 | Blank? N | Section Status: Entry Complete | | |
| Visit: WEEK 0 (BASELINE) | | Section Date: 23-05-2007 | | | | |
| Entered By: Christina Breedlove | | Entry Time: 30-07-2007 12:45:11 | | | | |
| | | Last Modification Time: 07-12-2007 18:42:43 | | | | |
| | | Page number: 13.1 | | | | |
| HDYF? INQUIRY | | | | | | |
| Date | Actual Time | HDYF Performed? | | Comments | | |
| 23-05-2007 | NR | YES | | | | |
| 24-05-2007 | 0520 | YES | | | | |

| | | | | | | | |
|---------------------------------|-------------|---------------------------------------------|-----------|--------------------------------|------------------|-------------|------|
| Section: Vital | | 7 of 11 | Blank? N | Section Status: Entry Complete | | | |
| Visit: WEEK 0 (BASELINE) | | Section Date: 23-05-2007 | | | | | |
| Entered By: Christina Breedlove | | Entry Time: 30-07-2007 12:45:11 | | | | | |
| | | Last Modification Time: 30-07-2007 13:52:27 | | | | | |
| | | Page number: 13.1 | | | | | |
| VITAL SIGNS | | | | | | | |
| | | Blood Pressure | | | | Oral | |
| Date | Actual Time | Systolic | Diastolic | Pulse | Respiratory Rate | Temperature | Unit |
| 23-05-2007 | 1729 | 108 | 073 | 081 | 16 | 036.9 | C |
| | | | | | | xxx.x | |
| Comments | | | | | | | |

CRF Report for Study E6270229

Patient: 3026

Site: CDB_001

Investigator: CDB_001

CRF: Week 0 Baseline

Blank? N

CRF Page #: 5

Visit: WEEK 0 (BASELINE)

Visit Date: 23-05-2007

Document #: R150976213

| | | | |
|---------------------------------|---------|---------------------------------------------|--------------------------------|
| Section: Oral_Health_Exam | 8 of 11 | Blank? N | Section Status: Entry Complete |
| Visit: WEEK 0 (BASELINE) | | Section Date: 23-05-2007 | |
| Entered By: Christina Breedlove | | Entry Time: 30-07-2007 12:45:11 | |
| | | Last Modification Time: 01-11-2007 20:40:27 | |
| | | Page number: 13.1 | |

| ORAL HEALTH EXAMINATION | | | |
|-------------------------|---------------------------------|---------------------|----------|
| Date | Procedure | Relevant Findings?* | Findings |
| 23-05-2007 | 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: 23-05-2007 | |
| Entered By: Christina Breedlove | | Entry Time: 30-07-2007 12:45:11 | |
| | | Last Modification Time: 07-12-2007 18:44:56 | |
| | | Page number: 14.1 | |

| PHYSICAL EXAMINATION | | | | |
|----------------------|-------------|-------------|--------------------|----------|
| Date | Code Number | Code | Relevant Findings? | Findings |
| 23-05-2007 | 01 | GENERAL | NO | |
| | 02 | SKIN | NO | |
| | 03 | HEENT | NO | |
| | 04 | MOUTH | NO | |
| | 05 | NECK | NO | |
| | 06 | THORAX/LUNG | NO | |
| | 07 | CARDIO | NO | |
| | 08 | ABDOMEN | NO | |
| | 09 | MUSCULO | NO | |
| | 10 | NEURO | NO | |
| | 11 | LYMPH | NO | |
| | 12 | OTHER | NE | |

| | | | |
|---------------------------------|----------|---------------------------------------------|--------------------------------|
| Section: Weight_Height | 10 of 11 | Blank? N | Section Status: Entry Complete |
| Visit: WEEK 0 (BASELINE) | | Section Date: 23-05-2007 | |
| Entered By: Christina Breedlove | | Entry Time: 30-07-2007 12:45:11 | |
| | | Last Modification Time: 30-07-2007 13:52:27 | |
| | | Page number: 14.1 | |

CRF Report for Study E6270229



Patient: 3026

CRF: Week 0 Baseline

Visit: WEEK 0 (BASELINE)

Site: CDB_001

Blank? N

Visit Date: 23-05-2007

Investigator: CDB_001

CRF Page #: 5

Document #: R150976213

| | | | | |
|------------------------|--------|----------|--------|------|
| Section: Weight_Height | | 10 of 11 | | |
| WEIGHT & HEIGHT | | | | |
| Date | Weight | Unit | Height | Unit |
| 23-05-2007 | 083.8 | KG | ND | |
| | xxx.x | | xxx.x | |

| | | | | | |
|---------------------------------|--|---------------------------------------------|--|----------|--------------------------------|
| Section: Lab_Eval | | 11 of 11 | | Blank? N | Section Status: Entry Complete |
| Visit: WEEK 0 (BASELINE) | | Section Date: 23-05-2007 | | | |
| Entered By: Christina Breedlove | | Entry Time: 30-07-2007 12:45:11 | | | |
| | | Last Modification Time: 07-12-2007 18:46:36 | | | |
| | | Page number: 15.1 | | | |

| Laboratory Evaluations | | | | |
|-------------------------------------------------|-----------|---------|----------------------|----------|
| Date | | | | |
| 24-05-2007 | | | | |
| Were the scheduled laboratory samples obtained? | | YES | No, specify | |
| Requisition Number 1 | | P060625 | | |
| Requisition Number 2 (if applicable) | | | | |
| Were there any clinically significant labs? | | NO | (Yes, specify below) | |
| 23-05-2007 | | | | |
| | | YES | | |
| P205166 | | | | |
| NO | | | | |
| Requisition Number | Test Name | H/L | Lab ID | Lab Name |

CRF Report for Study E6270229



Patient: 3026

CRF: Week 0 2baseline

Visit: WEEK 0 (BASELINE)

Entered By: Christina Breedlove

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? N

Visit Date: 23-05-2007

Entry Time: 30-07-2007 13:57:54

Modification Time: 09-12-2007 13:35:18

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 5.1

Document #: R150985913

CRF Status: Entry Complete

Approver:

Verifier:

| | | | |
|-------------------------------------------------------------------------------------|-------------|---------------------------------------------|--------------------------------|
| Section: Pk_Blood_Biomark | 1 of 11 | Blank? N | Section Status: Entry Complete |
| Visit: WEEK 0 (BASELINE) | | Section Date: 23-05-2007 | |
| Entered By: Christina Breedlove | | Entry Time: 30-07-2007 13:57:54 | |
| | | Last Modification Time: 30-07-2007 16:18:55 | |
| | | Page number: 15.1 | |
| Blood Sampling For Biomarkers/Chemistry/Hematology (following an overnight fast) | | | |
| Date | Actual Time | Comments | |
| 24-05-2007 | 0641 | | |

| | | | |
|---------------------------------|-------------|---------------------------------------------|--------------------------------|
| Section: Expired_Carbon_M | 2 of 11 | Blank? N | Section Status: Entry Complete |
| Visit: WEEK 0 (BASELINE) | | Section Date: 23-05-2007 | |
| Entered By: Christina Breedlove | | Entry Time: 30-07-2007 13:57:54 | |
| | | Last Modification Time: 30-07-2007 16:18:55 | |
| | | Page number: 15.1 | |
| EXPIRED CARBON MONOXIDE | | | |
| Date | Actual Time | ECO Level (ppm) | %COHb |
| 24-05-2007 | 1117 | 24 | 04.4 |

| | | | |
|---------------------------------|-------------|---------------------------------------------|--------------------------------|
| Section: Blood_Sampl_Cohb | 3 of 11 | Blank? N | Section Status: Entry Complete |
| Visit: WEEK 0 (BASELINE) | | Section Date: 23-05-2007 | |
| Entered By: Christina Breedlove | | Entry Time: 30-07-2007 13:57:54 | |
| | | Last Modification Time: 30-07-2007 16:18:55 | |
| | | Page number: 15.1 | |
| Blood Sampling for %COHb | | | |
| Date | Actual Time | Comments | |
| 24-05-2007 | 1120 | | |

| | | | |
|---------------------------------|---------|---------------------------------------------|--------------------------------|
| Section: Pre_Bronch_Spir | 4 of 11 | Blank? N | Section Status: Entry Complete |
| Visit: WEEK 0 (BASELINE) | | Section Date: 23-05-2007 | |
| Entered By: Christina Breedlove | | Entry Time: 30-07-2007 13:57:54 | |
| | | Last Modification Time: 09-12-2007 13:32:22 | |
| | | Page number: 16.1 | |

CRF Report for Study E6270229

Patient: 3026

CRF: Week 0 2baseline

Visit: WEEK 0 (BASELINE)

Site: CDB_001

Blank? N

Visit Date: 23-05-2007

Investigator: CDB_001

CRF Page #: 5.1

Document #: R150985913

| | | | | | | | |
|---------------------------------------------------------|------|------------------|--------|--------------------|-------|-------------------|----------|
| 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 |
| 24-05-2007 | 1525 | STANDI NG | 2.69 | 91 | 3.22 | 88 | |

| | | | | | | | |
|---------------------------------|----------------|---------------------------------------------|--|----------|--|--------------------------------|--|
| Section: Proventil_Admin | | 5 of 11 | | Blank? N | | Section Status: Entry Complete | |
| Visit: WEEK 0 (BASELINE) | | Section Date: 23-05-2007 | | | | | |
| Entered By: Christina Breedlove | | Entry Time: 30-07-2007 13:57:54 | | | | | |
| | | Last Modification Time: 30-07-2007 16:18:55 | | | | | |
| | | Page number: 16.1 | | | | | |
| PROVENTIL ADMINISTRATION | | | | | | | |
| Actual Time | | | | | | | |
| of Proventil | | | | | | | |
| Date | Administration | Amount Administered | | Comments | | | |
| 24-05-2007 | 1529 | 2 METERED PUFFS | | | | | |

| | | | | | | | |
|-------------------------------------------------|------|---------------------------------------------|--------|--------------------|-------|--------------------------------|----------|
| Section: Post_Bronch_Spir | | 6 of 11 | | Blank? N | | Section Status: Entry Complete | |
| Visit: WEEK 0 (BASELINE) | | Section Date: 23-05-2007 | | | | | |
| Entered By: Christina Breedlove | | Entry Time: 30-07-2007 13:57:54 | | | | | |
| | | Last Modification Time: 09-12-2007 13:35:18 | | | | | |
| | | 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 |
| 24-05-2007 | 1545 | STANDING | 2.70 | 92 | 3.09 | 84 | |

| | | | | | | | |
|----------------------------------------------|-------------------------------------------------------------------------------------|---------------------------------------------|--|----------|--|--------------------------------|-----|
| Section: Unused_Usual_Bra | | 7 of 11 | | Blank? N | | Section Status: Entry Complete | |
| Visit: WEEK 0 (BASELINE) | | Section Date: 23-05-2007 | | | | | |
| Entered By: Christina Breedlove | | Entry Time: 30-07-2007 13:57:54 | | | | | |
| | | Last Modification Time: 30-07-2007 16:18:55 | | | | | |
| | | Page number: 17.1 | | | | | |
| Unused Usual Brand Cigarette Pack Collection | | | | | | | |
| Yes / No | | | | | | | |
| Date | Does Site have 5 unopened packs of subject's usual brand cigarette to ship to CCLS? | | | | | | YES |
| 23-05-2007 | | | | | | | |

CRF Report for Study E6270229

Patient: 3026

CRF: Week 0 2baseline

Visit: WEEK 0 (BASELINE)

Site: CDB_001

Blank? N

Visit Date: 23-05-2007

Investigator: CDB_001

CRF Page #: 5.1

Document #: R150985913

| | | | | | | | |
|---------------------------------|--|---------|--|---------------------------------------------|--|--------------------------------|--|
| Section: Usual_Brand_Butt | | 8 of 11 | | Blank? N | | Section Status: Entry Complete | |
| Visit: WEEK 0 (BASELINE) | | | | Section Date: 23-05-2007 | | | |
| Entered By: Christina Breedlove | | | | Entry Time: 30-07-2007 13:57:54 | | | |
| | | | | Last Modification Time: 30-07-2007 16:18:55 | | | |
| | | | | Page number: 17.1 | | | |

| Usual Brand Cigarette Butt Collection | | | | | Number of Usual | | If yes, number of | |
|---------------------------------------|------------|------------|------------|-----------|-----------------------|-------------|-------------------|----------|
| Scheduled Collection | Start Date | Start Time | Stop Date | Stop Time | Brand Cigarette Butts | Any Product | butts other than | Comments |
| Period | | | | | Collected | Deviation? | usual brand: | |
| 24 HOURS PRIOR TO CHECK-IN | 22-05-2007 | 1600 | 23-05-2007 | 1600 | 13 | NO | | |
| 24 HOURS IN-HOUSE | 23-05-2007 | 1600 | 24-05-2007 | 1600 | 17 | NO | | |

| | | | | | | | |
|---------------------------------|--|---------|--|---------------------------------------------|--|--------------------------------|--|
| Section: Used_Butt_Measur | | 9 of 11 | | Blank? N | | Section Status: Entry Complete | |
| Visit: WEEK 0 (BASELINE) | | | | Section Date: 23-05-2007 | | | |
| Entered By: Christina Breedlove | | | | Entry Time: 30-07-2007 13:57:54 | | | |
| | | | | Last Modification Time: 30-07-2007 16:18:55 | | | |
| | | | | Page number: 18.1 | | | |

| USUAL BRAND CIGARETTE BUTT MEASUREMENT | | | | |
|----------------------------------------|----------------------------|--------|-----------------------|---------------------------------|
| Date | Scheduled Collection | Period | Cigarette Butt Number | Cigarette Butt Measurement (mm) |
| 23-05-2007 | 24 HOURS PRIOR TO CHECK-IN | | 1 | 48 |
| | | | 2 | 45 |
| | | | 3 | 48 |
| | | | 4 | 44 |
| | | | 5 | 45 |
| | | | 6 | 45 |
| | | | 7 | 43 |
| | | | 8 | 44 |
| | | | 9 | 53 |
| | | | 10 | 56 |
| | | | 11 | 45 |
| | | | 12 | 43 |
| | | | 13 | 48 |

| | | | | | | | |
|---------------------------------|--|----------|--|---------------------------------|--|--------------------------------|--|
| Section: Used_Butt_Measur | | 10 of 11 | | Blank? N | | Section Status: Entry Complete | |
| Visit: WEEK 0 (BASELINE) | | | | Section Date: 23-05-2007 | | | |
| Entered By: Christina Breedlove | | | | Entry Time: 30-07-2007 13:57:54 | | | |

CRF Report for Study E6270229

Patient: 3026

CRF: Week 0 2baseline

Visit: WEEK 0 (BASELINE)

Site: CDB_001

Blank? N

Visit Date: 23-05-2007

Investigator: CDB_001

CRF Page #: 5.1

Document #: R150985913

Section: Used_Butt_Measur 10 of 11

Last Modification Time: 30-07-2007 16:18:55

Page number: 19.1

USUAL BRAND CIGARETTE BUTT MEASUREMENT

Scheduled Collection

Date
24-05-2007

Period
24 HOURS IN-HOUSE

Cigarette Butt Number

Cigarette Butt Measurement (mm)

| | |
|----|----|
| 1 | 56 |
| 2 | 50 |
| 3 | 53 |
| 4 | 45 |
| 5 | 42 |
| 6 | 46 |
| 7 | 44 |
| 8 | 48 |
| 9 | 44 |
| 10 | 41 |
| 11 | 53 |
| 12 | 42 |
| 13 | 50 |
| 14 | 44 |
| 15 | 50 |
| 16 | 46 |
| 17 | 46 |

Section: Randomization 11 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 23-05-2007

Entered By: Christina Breedlove

Entry Time: 30-07-2007 13:57:54

Last Modification Time: 30-07-2007 16:18:55

Page number: 20.1

RANDOMIZATION

Date
24-05-2007

Actual Time
1552

Randomization Sequence
GROUP B

CRF Report for Study E6270229



Patient: 3026

CRF: Week 0 3baseline

Visit: WEEK 0 (BASELINE)

Entered By: Christina Breedlove

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? Y

Visit Date: 23-05-2007

Entry Time: 30-07-2007 16:18:56

Modification Time: 09-12-2007 13:24:51

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 5.2

Document #: R151014613

CRF Status: Created

Approver:

Verifier:

Section: Study_Prod_Dispe

Blank? Y

Section Status: Created

Visit: WEEK 0 (BASELINE)

Section Date: 23-05-2007

Entered By: Christina Breedlove

Entry Time: 30-07-2007 16:18:56

Last Modification Time: 09-12-2007 13:24:45

Page number: 23.1

STUDY PRODUCT DISPENSATION

Date

Actual Time

Product Dispensed

Flavor

Amount Dispensed

CRF Report for Study E6270229



Patient: 3026

CRF: Intercurrent_III

Visit: INTERCURRENT ILL

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? N

Visit Date: 03-05-2007

Entry Time: 07-12-2007 18:52:49

Modification Time: 09-12-2007 15:51:16

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 7

Document #: R169150913

CRF Status: Entry Complete

Approver:

Verifier:

Section: Ip_Findings

Blank? N

Section Status: Entry Complete

Visit: INTERCURRENT ILL

Section Date: 03-05-2007

Entered By: Melissa Zeis

Entry Time: 07-12-2007 18:52:49

Last Modification Time: 09-12-2007 15:51:16

Page number: 21

Intercurrent Illness/Physical Findings

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

NO

Onset

Resolved / Changed

Relationship

| Event No | Illness/Finding | Date | Time | Date | Time | Severity | Relationship to Procedure | Action Taken |
|----------|-----------------|------|------|------|------|----------|------------------------------|--------------|
|----------|-----------------|------|------|------|------|----------|------------------------------|--------------|

CRF Report for Study E6270229



Patient: 3026
CRF: Week 1
Visit: WEEK 1
Entered By: Melissa Zeis
Discrepancies: None
Approval Status: Not Approved
Verification: Not Verified
Comment:

Site: CDB_001
Blank? Y
Visit Date: 01-01-2001
Entry Time: 07-12-2007 18:52:55
Modification Time:
Approval Time:
Verification Time:

Investigator: CDB_001
CRF Page #: 8
Document #: R169151013
CRF Status: Created
Approver:
Verifier:

| | | | |
|---------------------------------------|-----------------|---------------------------------|-------------------------|
| Section: Hdyf_Oral_Health | 1 of 5 | Blank? Y | Section Status: Created |
| Visit: WEEK 1 | | Section Date: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:52:55 | |
| | | Last Modification Time: | |
| | | Page number: 22 | |
| HDYF? / ORAL HEALTH QUESTIONS INQUIRY | | | |
| | | Oral Health | |
| | | Questions | |
| Actual Time | HDYF Performed? | Performed? | Comments |

| | | | |
|--------------------------|----------------|---------------------------------|-------------------------|
| Section: Vital | 2 of 5 | Blank? Y | Section Status: Created |
| Visit: WEEK 1 | | Section Date: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:52:55 | |
| | | Last Modification Time: | |
| | | Page number: 22 | |
| VITAL SIGNS | | | |
| | Blood Pressure | | Oral |
| Actual Time | Systolic | Diastolic | Pulse |
| | | | Respiratory Rate |
| | | | Temperature |
| | | | xxx.x |
| Comments | | | Unit |

| | | | |
|---------------------------|-----------------|---------------------------------|-------------------------|
| Section: Expired_Carbon_M | 3 of 5 | Blank? Y | Section Status: Created |
| Visit: WEEK 1 | | Section Date: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:52:55 | |
| | | Last Modification Time: | |
| | | Page number: 22 | |
| EXPIRED CARBON MONOXIDE | | | |
| Actual Time | ECO Level (ppm) | %COHb | Comments |

| | | | |
|---------------------------|--------|---------------------------------|-------------------------|
| Section: Unused_Study_Pro | 4 of 5 | Blank? Y | Section Status: Created |
| Visit: WEEK 1 | | Section Date: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:52:55 | |
| | | Last Modification Time: | |

CRF Report for Study E6270229



Patient: 3026
CRF: Week 1
Visit: WEEK 1

Site: CDB_001
Blank? Y
Visit Date: 01-01-2001

Investigator: CDB_001
CRF Page #: 8
Document #: R169151013

| | | |
|-------------------------------|--------|----------------------------------------------------------|
| Section: Unused_Study_Pro | 4 of 5 | Page number: 23 |
| Unused Study Product Returned | | |
| Product Returned | Flavor | Amount Returned Packs Individual Cigarettes / pouches |

| | | | |
|----------------------------|---------------------------------|----------|-------------------------|
| Section: Study_Prod_Dispe | 5 of 5 | Blank? Y | Section Status: Created |
| Visit: WEEK 1 | Section Date: 01-01-2001 | | |
| Entered By: Melissa Zeis | Entry Time: 07-12-2007 18:52:55 | | |
| Last Modification Time: | | | |
| Page number: 23 | | | |
| STUDY PRODUCT DISPENSATION | | | |
| Actual Time | Product Dispensed | Flavor | Amount Dispensed |

CRF Report for Study E6270229



Patient: 3026
CRF: Week 2
Visit: WEEK 2
Entered By: Melissa Zeis
Discrepancies: None
Approval Status: Not Approved
Verification: Not Verified
Comment:

Site: CDB_001
Blank? Y
Visit Date: 01-01-2001
Entry Time: 07-12-2007 18:53:11
Modification Time:
Approval Time:
Verification Time:

Investigator: CDB_001
CRF Page #: 9
Document #: R169151113
CRF Status: Created
Approver:
Verifier:

| | | | |
|---------------------------------------|-----------------|---------------------------------|-------------------------|
| Section: Hdyf_Oral_Health | 1 of 6 | Blank? Y | Section Status: Created |
| Visit: WEEK 2 | | Section Date: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:53:11 | |
| | | Last Modification Time: | |
| | | Page number: 24 | |
| HDYF? / ORAL HEALTH QUESTIONS INQUIRY | | | |
| | | Oral Health Questions | |
| Actual Time | HDYF Performed? | Performed? | Comments |

| | | | |
|--------------------------|--------------------|---------------------------------|-------------------------|
| Section: Vital | 2 of 6 | Blank? Y | Section Status: Created |
| Visit: WEEK 2 | | Section Date: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:53:11 | |
| | | Last Modification Time: | |
| | | Page number: 24 | |
| VITAL SIGNS | | | |
| Actual Time | Blood Pressure | Oral Temperature | Unit |
| | Systolic Diastolic | xxx.x | |
| Comments | | | |

| | | | |
|---------------------------|-----------------|---------------------------------|-------------------------|
| Section: Expired_Carbon_M | 3 of 6 | Blank? Y | Section Status: Created |
| Visit: WEEK 2 | | Section Date: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:53:11 | |
| | | Last Modification Time: | |
| | | Page number: 24 | |
| EXPIRED CARBON MONOXIDE | | | |
| Actual Time | ECO Level (ppm) | %COHb | Comments |

| | | | |
|---------------------------|--------|---------------------------------|-------------------------|
| Section: Blood_Sampl_Cohb | 4 of 6 | Blank? Y | Section Status: Created |
| Visit: WEEK 2 | | Section Date: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:53:11 | |
| | | Last Modification Time: | |

CRF Report for Study E6270229

Patient: 3026
CRF: Week 2
Visit: WEEK 2

Site: CDB_001
Blank? Y
Visit Date: 01-01-2001

Investigator: CDB_001
CRF Page #: 9
Document #: R169151113

Section: Blood_Sampl_Cohb 4 of 6

Page number: 24

Blood Sampling for %COHb
Actual Time Comments

Section: Unused_Study_Pro 5 of 6

Blank? Y

Section Status: Created

Visit: WEEK 2

Section Date: 01-01-2001

Entered By: Melissa Zeis

Entry Time: 07-12-2007 18:53:11

Last Modification Time:

Page number: 25

Unused Study Product Returned

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

Section: Study_Prod_Dispe 6 of 6

Blank? Y

Section Status: Created

Visit: WEEK 2

Section Date: 01-01-2001

Entered By: Melissa Zeis

Entry Time: 07-12-2007 18:53:11

Last Modification Time:

Page number: 25

STUDY PRODUCT DISPENSATION

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

CRF Report for Study E6270229



Patient: 3026

CRF: Week 4

Visit: WEEK 4

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? Y

Visit Date: 01-01-2001

Entry Time: 07-12-2007 18:53:32

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 10

Document #: R169151313

CRF Status: Created

Approver:

Verifier:

| | | | |
|-----------------------------------------------------------------------------------------------------------------------------------------|--------|---------------------------------|-------------------------|
| Section: Pro_Questionnair | 1 of 6 | Blank? Y | Section Status: Created |
| Visit: WEEK 4 | | Section Date: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:53:32 | |
| | | Last Modification Time: | |
| | | Page number: 26 | |
| PRO QUESTIONNAIRES | | | |
| With the possible exception of urinating, did subject complete Smoker Core Questionnaire PRIOR to any study procedures being performed? | | | YES / NO |

| | | | |
|---------------------------------------|-----------------|---------------------------------|-------------------------|
| Section: Hdyf_Oral_Health | 2 of 6 | Blank? Y | Section Status: Created |
| Visit: WEEK 4 | | Section Date: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:53:32 | |
| | | Last Modification Time: | |
| | | Page number: 26 | |
| HDYF? / ORAL HEALTH QUESTIONS INQUIRY | | | |
| Oral Health Questions | | | |
| Actual Time | HDYF Performed? | Performed? | Comments |

| | | | |
|--------------------------|----------------|---------------------------------|-------------------------|
| Section: Vital | 3 of 6 | Blank? Y | Section Status: Created |
| Visit: WEEK 4 | | Section Date: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:53:32 | |
| | | Last Modification Time: | |
| | | Page number: 26 | |
| VITAL SIGNS | | | |
| Actual Time | Blood Pressure | Pulse | Respiratory Rate |
| | Systolic | Diastolic | Temperature |
| | | | xxx.x |
| Unit | | | |
| Comments | | | |

| | | | |
|---------------------------|--------|--------------------------|-------------------------|
| Section: Expired_Carbon_M | 4 of 6 | Blank? Y | Section Status: Created |
| Visit: WEEK 4 | | Section Date: 01-01-2001 | |

CRF Report for Study E6270229



Patient: 3026
CRF: Week 4
Visit: WEEK 4

Site: CDB_001
Blank? Y
Visit Date: 01-01-2001

Investigator: CDB_001
CRF Page #: 10
Document #: R169151313

Section: Expired_Carbon_M 4 of 6

Entered By: Melissa Zeis

Entry Time: 07-12-2007 18:53:32

Last Modification Time:

Page number: 26

EXPIRED CARBON MONOXIDE

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

Section: Unused_Study_Pro 5 of 6

Blank? Y

Section Status: Created

Visit: WEEK 4

Section Date: 01-01-2001

Entered By: Melissa Zeis

Entry Time: 07-12-2007 18:53:32

Last Modification Time:

Page number: 27

Unused Study Product Returned

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

Section: Study_Prod_Dispe 6 of 6

Blank? Y

Section Status: Created

Visit: WEEK 4

Section Date: 01-01-2001

Entered By: Melissa Zeis

Entry Time: 07-12-2007 18:53:32

Last Modification Time:

Page number: 27

STUDY PRODUCT DISPENSATION

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

CRF Report for Study E6270229

Patient: 3026

CRF: Week 6

Visit: WEEK 6

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? Y

Visit Date: 01-01-2001

Entry Time: 07-12-2007 18:53:41

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 11

Document #: R169151413

CRF Status: Created

Approver:

Verifier:

| | | | |
|---------------------------------------|-----------------|---------------------------------|-------------------------|
| Section: Hdyf_Oral_Health | 1 of 5 | Blank? Y | Section Status: Created |
| Visit: WEEK 6 | | Section Date: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:53:41 | |
| | | Last Modification Time: | |
| | | Page number: 28 | |
| HDYF? / ORAL HEALTH QUESTIONS INQUIRY | | | |
| Oral Health Questions | | | |
| Actual Time | HDYF Performed? | Performed? | Comments |

| | | | |
|---------------------------|-----------------|---------------------------------|-------------------------|
| Section: Expired_Carbon_M | 2 of 5 | Blank? Y | Section Status: Created |
| Visit: WEEK 6 | | Section Date: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:53:41 | |
| | | Last Modification Time: | |
| | | Page number: 28 | |
| EXPIRED CARBON MONOXIDE | | | |
| Actual Time | ECO Level (ppm) | %COHb | Comments |

| | | | |
|--------------------------|-------------------------|---------------------------------|-------------------------|
| Section: Vital | 3 of 5 | Blank? Y | Section Status: Created |
| Visit: WEEK 6 | | Section Date: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:53:41 | |
| | | Last Modification Time: | |
| | | Page number: 28 | |
| VITAL SIGNS | | | |
| Actual Time | Blood Pressure | Pulse | Respiratory Rate |
| | Systolic Diastolic | | |
| | | Oral Temperature | Unit |
| | | xxx.x | |
| Comments | | | |

| | | | |
|---------------------------|--------|---------------------------------|-------------------------|
| Section: Unused_Study_Pro | 4 of 5 | Blank? Y | Section Status: Created |
| Visit: WEEK 6 | | Section Date: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:53:41 | |
| | | Last Modification Time: | |

CRF Report for Study E6270229

Patient: 3026
CRF: Week 6
Visit: WEEK 6

Site: CDB_001
Blank? Y
Visit Date: 01-01-2001

Investigator: CDB_001
CRF Page #: 11
Document #: R169151413

Section: Unused_Study_Pro 4 of 5

Page number: 29

Unused Study Product Returned

Product Returned

Flavor

Amount Returned

Packs

Individual Cigarettes / pouches

Section: Study_Prod_Dispe 5 of 5

Blank? Y

Section Status: Created

Visit: WEEK 6

Section Date: 01-01-2001

Entered By: Melissa Zeis

Entry Time: 07-12-2007 18:53:41

Last Modification Time:

Page number: 29

STUDY PRODUCT DISPENSATION

Actual Time

Product Dispensed

Flavor

Amount Dispensed

CRF Report for Study E6270229



Patient: 3026
 CRF: Week 8
 Visit: WEEK 8
 Entered By: Melissa Zeis
 Discrepancies: None
 Approval Status: Not Approved
 Verification: Not Verified
 Comment:

Site: CDB_001
 Blank? Y
 Visit Date: 01-01-2001
 Entry Time: 07-12-2007 18:53:51
 Modification Time:
 Approval Time:
 Verification Time:

Investigator: CDB_001
 CRF Page #: 13
 Document #: R169151513
 CRF Status: Created
 Approver:
 Verifier:

| | | | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|---------------------------------|-------------------------|
| Section: Pro_Questionnair | 1 of 6 | Blank? Y | Section Status: Created |
| Visit: WEEK 8 | | Section Date: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:53:51 | |
| | | Last Modification Time: | |
| | | Page number: 30 | |
| PRO QUESTIONNAIRES With the possible exception of urinating, did subject complete Smoker Core Questionnaire PRIOR to any study procedures being performed? | | | |
| | | | YES / NO |

| | | | |
|--------------------------------------------------------------------------|-----------------|---------------------------------|-------------------------|
| Section: Hdyf_Oral_Health | 2 of 6 | Blank? Y | Section Status: Created |
| Visit: WEEK 8 | | Section Date: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:53:51 | |
| | | Last Modification Time: | |
| | | Page number: 30 | |
| HDYF? / ORAL HEALTH QUESTIONS INQUIRY Oral Health Questions | | | |
| Actual Time | HDYF Performed? | Performed? | Comments |

| | | | |
|--------------------------|-------------------------|---------------------------------|---------------------------|
| Section: Vital | 3 of 6 | Blank? Y | Section Status: Created |
| Visit: WEEK 8 | | Section Date: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:53:51 | |
| | | Last Modification Time: | |
| | | Page number: 30 | |
| VITAL SIGNS | | | |
| Actual Time | Blood Pressure | Pulse | Respiratory Rate |
| | Systolic Diastolic | | Oral Temperature xxx.x |
| | | Unit | |
| Comments | | | |

| | | | |
|---------------------------|--------|--------------------------|-------------------------|
| Section: Expired_Carbon_M | 4 of 6 | Blank? Y | Section Status: Created |
| Visit: WEEK 8 | | Section Date: 01-01-2001 | |

CRF Report for Study E6270229

Patient: 3026
CRF: Week 8
Visit: WEEK 8

Site: CDB_001
Blank? Y
Visit Date: 01-01-2001

Investigator: CDB_001
CRF Page #: 13
Document #: R169151513

Section: Expired_Carbon_M 4 of 6

Entered By: Melissa Zeis

Entry Time: 07-12-2007 18:53:51

Last Modification Time:

Page number: 30

EXPIRED CARBON MONOXIDE

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

Section: Unused_Study_Pro 5 of 6

Blank? Y

Section Status: Created

Visit: WEEK 8

Section Date: 01-01-2001

Entered By: Melissa Zeis

Entry Time: 07-12-2007 18:53:51

Last Modification Time:

Page number: 31

Unused Study Product Returned

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

Section: Study_Prod_Dispe 6 of 6

Blank? Y

Section Status: Created

Visit: WEEK 8

Section Date: 01-01-2001

Entered By: Melissa Zeis

Entry Time: 07-12-2007 18:53:51

Last Modification Time:

Page number: 31

STUDY PRODUCT DISPENSATION

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

CRF Report for Study E6270229

Patient: 3026

CRF: Week 10

Visit: WEEK 10

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? Y

Visit Date: 01-01-2001

Entry Time: 07-12-2007 18:53:58

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 14

Document #: R169151613

CRF Status: Created

Approver:

Verifier:

| | | | |
|---------------------------------------|-----------------|---------------------------------|-------------------------|
| Section: Hdyf_Oral_Health | 1 of 5 | Blank? Y | Section Status: Created |
| Visit: WEEK 10 | | Section Date: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:53:58 | |
| | | Last Modification Time: | |
| | | Page number: 32 | |
| HDYF? / ORAL HEALTH QUESTIONS INQUIRY | | | |
| | | Oral Health | |
| | | Questions | |
| Actual Time | HDYF Performed? | Performed? | Comments |

| | | | |
|---------------------------|-----------------|---------------------------------|-------------------------|
| Section: Expired_Carbon_M | 2 of 5 | Blank? Y | Section Status: Created |
| Visit: WEEK 10 | | Section Date: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:53:58 | |
| | | Last Modification Time: | |
| | | Page number: 32 | |
| EXPIRED CARBON MONOXIDE | | | |
| Actual Time | ECO Level (ppm) | %COHb | Comments |

| | | | |
|--------------------------|----------------|---------------------------------|-------------------------|
| Section: Vital | 3 of 5 | Blank? Y | Section Status: Created |
| Visit: WEEK 10 | | Section Date: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:53:58 | |
| | | Last Modification Time: | |
| | | Page number: 32 | |
| VITAL SIGNS | | | |
| Actual Time | Blood Pressure | Oral | |
| | Systolic | Diastolic | |
| | Pulse | Respiratory Rate | |
| | | Temperature | |
| | | xxx.x | |
| Unit | | | |
| Comments | | | |

| | | | |
|---------------------------|--------|---------------------------------|-------------------------|
| Section: Unused_Study_Pro | 4 of 5 | Blank? Y | Section Status: Created |
| Visit: WEEK 10 | | Section Date: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:53:58 | |
| | | Last Modification Time: | |

CRF Report for Study E6270229



Patient: 3026
CRF: Week 10
Visit: WEEK 10

Site: CDB_001
Blank? Y
Visit Date: 01-01-2001

Investigator: CDB_001
CRF Page #: 14
Document #: R169151613

| | | |
|-------------------------------|--------|----------------------------------------------------------|
| Section: Unused_Study_Pro | 4 of 5 | Page number: 33 |
| Unused Study Product Returned | | |
| Product Returned | Flavor | Amount Returned Packs Individual Cigarettes / pouches |

| | | | |
|----------------------------|---------------------------------|----------|-------------------------|
| Section: Study_Prod_Dispe | 5 of 5 | Blank? Y | Section Status: Created |
| Visit: WEEK 10 | Section Date: 01-01-2001 | | |
| Entered By: Melissa Zeis | Entry Time: 07-12-2007 18:53:58 | | |
| Last Modification Time: | | | |
| Page number: 33 | | | |
| STUDY PRODUCT DISPENSATION | | | |
| Actual Time | Product Dispensed | Flavor | Amount Dispensed |

CRF Report for Study E6270229



Patient: 3026

CRF: Week 12

Visit: WEEK 12

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? Y

Visit Date: 01-01-2001

Entry Time: 07-12-2007 18:54:09

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 15

Document #: R169151713

CRF Status: Created

Approver:

Verifier:

| | | | |
|---------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|-------------------------|
| Section: Pro_Questionnair | 1 of 11 | Blank? Y | Section Status: Created |
| Visit: WEEK 12 | | Section Date: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:54:09 | |
| | | Last Modification Time: | |
| | | Page number: 34 | |
| PRO QUESTIONNAIRES | | | |
| Date | 1. With the possible exception of urinating, did subject complete Smoker Routine Questionnaire PRIOR to any study procedures being performed? | YES / NO | |

| | | | |
|--------------------------|--------------------|---------------------------------|-------------------------|
| Section: Urine_Drug | 2 of 11 | Blank? Y | Section Status: Created |
| Visit: WEEK 12 | | Section Date: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:54:09 | |
| | | Last Modification Time: | |
| | | Page number: 34 | |
| Drug Screen | | | |
| Date | Drug Screen Result | | |

| | | | |
|--------------------------|---------------------|---------------------------------|-------------------------|
| Section: Alcohol_Screen | 3 of 11 | Blank? Y | Section Status: Created |
| Visit: WEEK 12 | | Section Date: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:54:09 | |
| | | Last Modification Time: | |
| | | Page number: 34 | |
| Alcohol Screen | | | |
| Date | Breathalyzer Result | | |

| | | | |
|--------------------------|---------|---------------------------------|-------------------------|
| Section: Preg_Test | 4 of 11 | Blank? Y | Section Status: Created |
| Visit: WEEK 12 | | Section Date: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:54:09 | |
| | | Last Modification Time: | |
| | | Page number: 34 | |
| Pregnancy Test | | | |

CRF Report for Study E6270229

Patient: 3026
CRF: Week 12
Visit: WEEK 12

Site: CDB_001
Blank? Y
Visit Date: 01-01-2001

Investigator: CDB_001
CRF Page #: 15
Document #: R169151713

| | |
|--------------------|---------|
| Section: Preg_Test | 4 of 11 |
| Date | Result |

| | | | |
|--------------------------|--------------------------|---------------------------------|-------------------------|
| Section: Urine_Coll | 5 of 11 | Blank? Y | Section Status: Created |
| Visit: WEEK 12 | Section Date: 01-01-2001 | Entry Time: 07-12-2007 18:54:09 | |
| Entered By: Melissa Zeis | Last Modification Time: | Page number: 34 | |
| 24-Hour Urine Collection | | | |
| Scheduled Timepoint | Start Date | Start Time | Stop Date |
| | | | Stop Time |
| | | | Total Volume |
| | | | Comments |

| | | | |
|---------------------------|--------------------------|---------------------------------|-------------------------|
| Section: Hdyl_Oral_Health | 6 of 11 | Blank? Y | Section Status: Created |
| Visit: WEEK 12 | Section Date: 01-01-2001 | Entry Time: 07-12-2007 18:54:09 | |
| Entered By: Melissa Zeis | Last Modification Time: | Page number: 35 | |
| HDYF? INQUIRY | | | |
| Date | Actual Time | HDYF Performed? | Comments |

| | | | |
|--------------------------|--------------------------|---------------------------------|-------------------------|
| Section: Vital | 7 of 11 | Blank? Y | Section Status: Created |
| Visit: WEEK 12 | Section Date: 01-01-2001 | Entry Time: 07-12-2007 18:54:09 | |
| Entered By: Melissa Zeis | Last Modification Time: | Page number: 35 | |
| VITAL SIGNS | | | |
| | | Blood Pressure | Oral Temperature |
| Date | Actual Time | Systolic | Diastolic |
| | | Pulse | Respiratory Rate |
| | | | Unit |
| | | | xxx.x |
| Comments | | | |

| | | | |
|---------------------------|--------------------------|---------------------------------|-------------------------|
| Section: Oral_Health_Exam | 8 of 11 | Blank? Y | Section Status: Created |
| Visit: WEEK 12 | Section Date: 01-01-2001 | Entry Time: 07-12-2007 18:54:09 | |
| Entered By: Melissa Zeis | Last Modification Time: | Page number: 35 | |
| ORAL HEALTH EXAMINATION | | | |

CRF Report for Study E6270229

Patient: 3026
CRF: Week 12
Visit: WEEK 12

Site: CDB_001
Blank? Y
Visit Date: 01-01-2001

Investigator: CDB_001
CRF Page #: 15
Document #: R169151713

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

| | | | |
|--------------------------|-------------|---------------------------------|-------------------------|
| Section: Phys_Exam | 9 of 11 | Blank? Y | Section Status: Created |
| Visit: WEEK 12 | | Section Date: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:54:09 | |
| | | Last Modification Time: | |
| | | Page number: 36 | |
| PHYSICAL EXAMINATION | | | |
| Date | Code Number | Code | Relevant Findings? |
| | | | Findings |

| | | | |
|--------------------------|----------|---------------------------------|-------------------------|
| Section: Weight_Height | 10 of 11 | Blank? Y | Section Status: Created |
| Visit: WEEK 12 | | Section Date: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:54:09 | |
| | | Last Modification Time: | |
| | | Page number: 36 | |
| WEIGHT & HEIGHT | | | |
| Date | Weight | Unit | Height |
| | xxx.x | | xxx.x |

| | | | |
|-------------------------------------------------|----------------------|---------------------------------|-------------------------|
| Section: Lab_Eval | 11 of 11 | Blank? Y | Section Status: Created |
| Visit: WEEK 12 | | Section Date: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:54:09 | |
| | | Last Modification Time: | |
| | | Page number: 37 | |
| Laboratory Evaluations | | | |
| Date | | | |
| Were the scheduled laboratory samples obtained? | No, specify | | |
| Requisition Number 1 | | | |
| Requisition Number 2 (if applicable) | | | |
| Were there any clinically significant labs? | (Yes, specify below) | | |
| Requisition Number | Test Name | H/L | Lab ID |
| | | | Lab Name |

CRF Report for Study E6270229



| | | |
|-------------------------------|---------------------------------|------------------------|
| Patient: 3026 | Site: CDB_001 | Investigator: CDB_001 |
| CRF: Week 12(2) | Blank? Y | CRF Page #: 16 |
| Visit: WEEK 12 | Visit Date: 01-01-2001 | Document #: R169151813 |
| Entered By: Melissa Zeis | Entry Time: 07-12-2007 18:54:17 | CRF Status: Created |
| Discrepancies: None | Modification Time: | Approver: |
| Approval Status: Not Approved | Approval Time: | Verifier: |
| Verification: Not Verified | Verification Time: | |
| Comment: | | |

| | | | |
|-------------------------------------------------------------------------------------|-------------|---------------------------------|-------------------------|
| Section: Pk_Blood_Biomark | 1 of 11 | Blank? Y | Section Status: Created |
| Visit: WEEK 12 | | Section Date: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:54:17 | |
| | | Last Modification Time: | |
| | | Page number: 37 | |
| Blood Sampling For Biomarkers/Chemistry/Hematology (following an overnight fast) | | | |
| Date | Actual Time | Comments | |

| | | | |
|---------------------------|-------------|---------------------------------|-------------------------|
| Section: Expired_Carbon_M | 2 of 11 | Blank? Y | Section Status: Created |
| Visit: WEEK 12 | | Section Date: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:54:17 | |
| | | Last Modification Time: | |
| | | Page number: 37 | |
| EXPIRED CARBON MONOXIDE | | | |
| Date | Actual Time | ECO Level (ppm) | %COHb |
| Comments | | | |

| | | | |
|---------------------------|-------------|---------------------------------|-------------------------|
| Section: Blood_Sampl_Cohb | 3 of 11 | Blank? Y | Section Status: Created |
| Visit: WEEK 12 | | Section Date: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:54:17 | |
| | | Last Modification Time: | |
| | | Page number: 37 | |
| Blood Sampling for %COHb | | | |
| Date | Actual Time | Comments | |

| | | | |
|---------------------------------------------------------|-------------|---------------------------------|-------------------------|
| Section: Pre_Bronch_Spir | 4 of 11 | Blank? Y | Section Status: Created |
| Visit: WEEK 12 | | Section Date: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:54:17 | |
| | | Last Modification Time: | |
| | | Page number: 38 | |
| PRE-BRONCHODILATOR BEST BASELINE SPIROMETRY TEST RESULT | | | |
| Date | Actual Time | Comments | |

CRF Report for Study E6270229

Patient: 3026

CRF: Week 12(2)

Visit: WEEK 12

Site: CDB_001

Blank? Y

Visit Date: 01-01-2001

Investigator: CDB_001

CRF Page #: 16

Document #: R169151813

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

| | | | |
|--------------------------|-------------------------|---------------------------------|-------------------------|
| Section: Proventil_Admin | 5 of 11 | Blank? Y | Section Status: Created |
| Visit: WEEK 12 | | Section Date: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:54:17 | |
| | Last Modification Time: | | |
| | Page number: 38 | | |
| PROVENTIL ADMINISTRATION | | | |
| Actual Time | | | |
| of Proventil | | | |
| Date | Administration | Amount Administered | Comments |

| | | | |
|-------------------------------------------------|----------------------------|---------------------------------|-------------------------|
| Section: Post_Bronch_Spir | 6 of 11 | Blank? Y | Section Status: Created |
| Visit: WEEK 12 | | Section Date: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:54:17 | |
| | | Last Modification Time: | |
| | | Page number: 38 | |
| POST-BRONCHODILATOR BEST SPIROMETRY TEST RESULT | | | |
| | Actual Time of FEV1/FVC | Testing | |
| Date | Test | Position | |
| | | FEV1 L | FEV1 Predicted (%) |
| | | FVC L | FVC Predicted (%) |
| | | | Comments |

| | | | | | | | | | |
|-------------------------------------------------|--|------------|--|------------------------------------------------------|--|------------------------------------|--|--------------------------|--|
| Section: Used Study Tobac | | 7 of 11 | | Blank? Y | | Section Status: Created | | | |
| Visit: WEEK 12 | | | | Section Date: 01-01-2001 | | | | | |
| Entered By: Melissa Zeis | | | | Entry Time: 07-12-2007 18:54:17 | | | | | |
| | | | | Last Modification Time: | | | | | |
| | | | | Page number: 39 | | | | | |
| USED STUDY TOBACCO-HEATING CIGARETTE COLLECTION | | | | | | | | | |
| | | | | Number of Study Tobacco-Heating Cigarettes Collected | | Weight of Cigarettes Collected (g) | | Any Product Deviation? | |
| Scheduled Collection Timepoint | | Start Date | | Start Time | | Stop Date | | Stop Time | |
| | | | | | | | | If yes, # of other Brand | |
| | | | | | | | | Comments | |

| | | | |
|--------------------------|---------|---------------------------------|-------------------------|
| Section: Used_Study_Snus | 8 of 11 | Blank? Y | Section Status: Created |
| Visit: WEEK 12 | | Section Date: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:54:17 | |

CRF Report for Study E6270229



Patient: 3026
CRF: Week 12(2)
Visit: WEEK 12

Site: CDB_001
Blank? Y
Visit Date: 01-01-2001

Investigator: CDB_001
CRF Page #: 16
Document #: R169151813

Section: Used_Study_Snus 8 of 11

Last Modification Time:

Page number: 40

USED STUDY SNUS COLLECTION

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

Section: Used_Study_Bum 9 of 11

Blank? Y

Section Status: Created

Visit: WEEK 12

Section Date: 01-01-2001

Entered By: Melissa Zeis

Entry Time: 07-12-2007 18:54:17

Last Modification Time:

Page number: 41

USED STUDY TOBACCO-BURNING CIGARETTE COLLECTION

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

Section: Used_Butt_Measur 10 of 11

Blank? Y

Section Status: Created

Visit: WEEK 12

Section Date: 01-01-2001

Entered By: Melissa Zeis

Entry Time: 07-12-2007 18:54:17

Last Modification Time:

Page number: 42

USUAL STUDY TOBACCO-BURNING CIGARETTE BUTT MEASUREMENT

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

Section: Used_Butt_Measur 11 of 11

Blank? Y

Section Status: Created

Visit: WEEK 12

Section Date: 01-01-2001

Entered By: Melissa Zeis

Entry Time: 07-12-2007 18:54:17

Last Modification Time:

Page number: 43

USED STUDY TOBACCO-BURNING CIGARETTE BUTT MEASUREMENT

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

CRF Report for Study E6270229



| | | |
|-------------------------------|---------------------------------|------------------------|
| Patient: 3026 | Site: CDB_001 | Investigator: CDB_001 |
| CRF: Week 12(3) | Blank? Y | CRF Page #: 17 |
| Visit: WEEK 12 | Visit Date: 01-01-2001 | Document #: R169151913 |
| Entered By: Melissa Zeis | Entry Time: 07-12-2007 18:54:25 | 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 | 1 of 2 | Blank? Y | Section Status: Created |
| Visit: WEEK 12 | Section Date: 01-01-2001 | | |
| Entered By: Melissa Zeis | Entry Time: 07-12-2007 18:54:25 | | |
| | Last Modification Time: | | |
| | Page number: 44 | | |
| Unused Study Product Returned | | | |
| Date | Actual Time | Product Returned | Flavor |
| | | | Amount Returned |
| | | | Packs Individual Cigarettes / pouches |

| | | | |
|----------------------------|---------------------------------|-------------------|-------------------------|
| Section: Study_Prod_Dispe | 2 of 2 | Blank? Y | Section Status: Created |
| Visit: WEEK 12 | Section Date: 01-01-2001 | | |
| Entered By: Melissa Zeis | Entry Time: 07-12-2007 18:54:25 | | |
| | Last Modification Time: | | |
| | Page number: 44 | | |
| STUDY PRODUCT DISPENSATION | | | |
| Date | Actual Time | Product Dispensed | Flavor |
| | | | Amount Dispensed |

CRF Report for Study E6270229



Patient: 3026
 CRF: Week 14
 Visit: WEEK 14
 Entered By: Melissa Zeis
 Discrepancies: None
 Approval Status: Not Approved
 Verification: Not Verified
 Comment:

Site: CDB_001
 Blank? Y
 Visit Date: 01-01-2001
 Entry Time: 07-12-2007 18:54:33
 Modification Time:
 Approval Time:
 Verification Time:

Investigator: CDB_001
 CRF Page #: 18
 Document #: R169152013
 CRF Status: Created
 Approver:
 Verifier:

| | | | | |
|---------------------------------------|-----------------|---------------------------------|-------------------------|--|
| Section: HDYf_Oral_Health | 1 of 5 | Blank? Y | Section Status: Created | |
| Visit: WEEK 14 | | Section Date: 01-01-2001 | | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:54:33 | | |
| | | Last Modification Time: | | |
| | | Page number: 45 | | |
| HDYF? / ORAL HEALTH QUESTIONS INQUIRY | | | | |
| | | Oral Health | | |
| | | Questions | | |
| Actual Time | HDYF Performed? | Performed? | Comments | |

| | | | | |
|---------------------------|-----------------|---------------------------------|-------------------------|--|
| Section: Expired_Carbon_M | 2 of 5 | Blank? Y | Section Status: Created | |
| Visit: WEEK 14 | | Section Date: 01-01-2001 | | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:54:33 | | |
| | | Last Modification Time: | | |
| | | Page number: 45 | | |
| EXPIRED CARBON MONOXIDE | | | | |
| Actual Time | ECO Level (ppm) | %COHb | Comments | |

| | | | | | |
|--------------------------|----------------|---------------------------------|-------------------------|------------------|----------------------|
| Section: Vital | 3 of 5 | Blank? Y | Section Status: Created | | |
| Visit: WEEK 14 | | Section Date: 01-01-2001 | | | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:54:33 | | | |
| | | Last Modification Time: | | | |
| | | Page number: 45 | | | |
| VITAL SIGNS | | | | | |
| | Blood Pressure | | | Oral | |
| Actual Time | Systolic | Diastolic | Pulse | Respiratory Rate | Temperature xxx.x |
| Unit | | | | | |
| Comments | | | | | |

| | | | | | |
|---------------------------|--------|---------------------------------|-------------------------|--|--|
| Section: Unused_Study_Pro | 4 of 5 | Blank? Y | Section Status: Created | | |
| Visit: WEEK 14 | | Section Date: 01-01-2001 | | | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:54:33 | | | |
| | | Last Modification Time: | | | |

CRF Report for Study E6270229

Patient: 3026
CRF: Week 14
Visit: WEEK 14

Site: CDB_001
Blank? Y
Visit Date: 01-01-2001

Investigator: CDB_001
CRF Page #: 18
Document #: R169152013

| | | |
|-------------------------------|--------|----------------------------------------------------------|
| Section: Unused_Study_Pro | 4 of 5 | Page number: 46 |
| Unused Study Product Returned | | |
| Product Returned | Flavor | Amount Returned Packs Individual Cigarettes / pouches |

| | | | |
|----------------------------|-------------------|---------------------------------|-------------------------|
| Section: Study_Prod_Dispe | 5 of 5 | Blank? Y | Section Status: Created |
| Visit: WEEK 14 | | Section Date: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:54:33 | |
| | | Last Modification Time: | |
| | | Page number: 46 | |
| STUDY PRODUCT DISPENSATION | | | |
| Actual Time | Product Dispensed | Flavor | Amount Dispensed |

CRF Report for Study E6270229

Patient: 3026
 CRF: Week 16
 Visit: WEEK 16
 Entered By: Melissa Zeis
 Discrepancies: None
 Approval Status: Not Approved
 Verification: Not Verified
 Comment:

Site: CDB_001
 Blank? Y
 Visit Date: 01-01-2001
 Entry Time: 07-12-2007 18:54:41
 Modification Time:
 Approval Time:
 Verification Time:

Investigator: CDB_001
 CRF Page #: 19
 Document #: R169152113
 CRF Status: Created
 Approver:
 Verifier:

| | | | |
|-----------------------------------------------------------------------------------------------------------------------------------------|--------|---------------------------------|-------------------------|
| Section: Pro_Questionnair | 1 of 6 | Blank? Y | Section Status: Created |
| Visit: WEEK 16 | | Section Date: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:54:41 | |
| | | 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: Hdvf_Oral_Health | 2 of 6 | Blank? Y | Section Status: Created |
| Visit: WEEK 16 | | Section Date: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:54:41 | |
| | | 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: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:54:41 | |
| | | Last Modification Time: | |
| | | Page number: 47 | |
| VITAL SIGNS | | | |
| Actual Time | Blood Pressure | Pulse | Respiratory Rate |
| | Systolic Diastolic | | Oral Temperature |
| | | | xxx.x |
| Unit | | | |
| Comments | | | |

| | | | |
|---------------------------|--------|--------------------------|-------------------------|
| Section: Expired_Carbon_M | 4 of 6 | Blank? Y | Section Status: Created |
| Visit: WEEK 16 | | Section Date: 01-01-2001 | |

CRF Report for Study E6270229

Patient: 3026
CRF: Week 16
Visit: WEEK 16

Site: CDB_001
Blank? Y
Visit Date: 01-01-2001

Investigator: CDB_001
CRF Page #: 19
Document #: R169152113

Section: Expired_Carbon_M 4 of 6

Entered By: Melissa Zeis

Entry Time: 07-12-2007 18:54:41

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: 01-01-2001

Entered By: Melissa Zeis

Entry Time: 07-12-2007 18:54:41

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: 01-01-2001

Entered By: Melissa Zeis

Entry Time: 07-12-2007 18:54:41

Last Modification Time:

Page number: 48

STUDY PRODUCT DISPENSATION

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

CRF Report for Study E6270229



Patient: 3026
 CRF: Week 18
 Visit: WEEK 18
 Entered By: Melissa Zeis
 Discrepancies: None
 Approval Status: Not Approved
 Verification: Not Verified
 Comment:

Site: CDB_001
 Blank? Y
 Visit Date: 01-01-2001
 Entry Time: 07-12-2007 18:54:49
 Modification Time:
 Approval Time:
 Verification Time:

Investigator: CDB_001
 CRF Page #: 20
 Document #: R169152213
 CRF Status: Created
 Approver:
 Verifier:

| | | | |
|---------------------------------------|-----------------|---------------------------------|-------------------------|
| Section: Hdyf_Oral_Health | 1 of 5 | Blank? Y | Section Status: Created |
| Visit: WEEK 18 | | Section Date: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:54:49 | |
| | | Last Modification Time: | |
| | | Page number: 49 | |
| HDYF? / ORAL HEALTH QUESTIONS INQUIRY | | | |
| | | Oral Health | |
| | | Questions | |
| Actual Time | HDYF Performed? | Performed? | Comments |

| | | | |
|---------------------------|-----------------|---------------------------------|-------------------------|
| Section: Expired_Carbon_M | 2 of 5 | Blank? Y | Section Status: Created |
| Visit: WEEK 18 | | Section Date: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:54:49 | |
| | | 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: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:54:49 | |
| | | Last Modification Time: | |
| | | Page number: 49 | |
| VITAL SIGNS | | | |
| | Blood Pressure | | |
| Actual Time | Systolic | Diastolic | Pulse |
| | | | Respiratory Rate |
| | | | Oral Temperature |
| | | | xxx.x |
| Unit | | | |
| Comments | | | |

| | | | |
|---------------------------|--------|---------------------------------|-------------------------|
| Section: Unused_Study_Pro | 4 of 5 | Blank? Y | Section Status: Created |
| Visit: WEEK 18 | | Section Date: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:54:49 | |
| | | Last Modification Time: | |

CRF Report for Study E6270229

Patient: 3026

CRF: Week 18

Visit: WEEK 18

Site: CDB_001

Blank? Y

Visit Date: 01-01-2001

Investigator: CDB_001

CRF Page #: 20

Document #: R169152213

| | | |
|---------------------------|--------|-----------------|
| 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: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:54:49 | |
| | | Last Modification Time: | |
| | | Page number: 50 | |

| STUDY PRODUCT DISPENSATION | | | |
|----------------------------|-------------------|--------|------------------|
| Actual Time | Product Dispensed | Flavor | Amount Dispensed |

CRF Report for Study E6270229



Patient: 3026

CRF: Week 20

Visit: WEEK 20

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? Y

Visit Date: 01-01-2001

Entry Time: 07-12-2007 18:54:57

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 21

Document #: R169152313

CRF Status: Created

Approver:

Verifier:

| | | | |
|-----------------------------------------------------------------------------------------------------------------------------------------|--------|---------------------------------|-------------------------|
| Section: Pro_Questionnaire | 1 of 6 | Blank? Y | Section Status: Created |
| Visit: WEEK 20 | | Section Date: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:54:57 | |
| | | 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: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:54:57 | |
| | | 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: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:54:57 | |
| | | Last Modification Time: | |
| | | Page number: 51 | |
| VITAL SIGNS | | | |
| Actual Time | Blood Pressure | Pulse | Respiratory Rate |
| | Systolic | Diastolic | Oral Temperature |
| | | | xxx.x |
| Unit | | | |
| Comments | | | |

| | | | |
|---------------------------|--------|--------------------------|-------------------------|
| Section: Expired_Carbon_M | 4 of 6 | Blank? Y | Section Status: Created |
| Visit: WEEK 20 | | Section Date: 01-01-2001 | |

CRF Report for Study E6270229

Patient: 3026
CRF: Week 20
Visit: WEEK 20

Site: CDB_001
Blank? Y
Visit Date: 01-01-2001

Investigator: CDB_001
CRF Page #: 21
Document #: R169152313

Section: Expired_Carbon_M 4 of 6

Entered By: Melissa Zeis

Entry Time: 07-12-2007 18:54:57

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: 01-01-2001

Entered By: Melissa Zeis

Entry Time: 07-12-2007 18:54:57

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: 01-01-2001

Entered By: Melissa Zeis

Entry Time: 07-12-2007 18:54:57

Last Modification Time:

Page number: 52

STUDY PRODUCT DISPENSATION

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

CRF Report for Study E6270229



| | | |
|-------------------------------|---------------------------------|------------------------|
| Patient: 3026 | Site: CDB_001 | Investigator: CDB_001 |
| CRF: Week 22 | Blank? Y | CRF Page #: 22 |
| Visit: WEEK 22 | Visit Date: 01-01-2001 | Document #: R169152413 |
| Entered By: Melissa Zeis | Entry Time: 07-12-2007 18:55:05 | CRF Status: Created |
| Discrepancies: None | Modification Time: | Approver: |
| Approval Status: Not Approved | Approval Time: | Verifier: |
| Verification: Not Verified | Verification Time: | |
| Comment: | | |

| | | | | |
|---------------------------------------|-----------------|---------------------------------|----------|-------------------------|
| Section: Hdyf_Oral_Health | | 1 of 5 | Blank? Y | Section Status: Created |
| Visit: WEEK 22 | | Section Date: 01-01-2001 | | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:55:05 | | |
| | | Last Modification Time: | | |
| | | Page number: 53 | | |
| HDYF? / ORAL HEALTH QUESTIONS INQUIRY | | | | |
| Oral Health Questions | | | | |
| Actual Time | HDYF Performed? | Performed? | Comments | |

| | | | | |
|---------------------------|-----------------|---------------------------------|----------|-------------------------|
| Section: Expired_Carbon_M | | 2 of 5 | Blank? Y | Section Status: Created |
| Visit: WEEK 22 | | Section Date: 01-01-2001 | | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:55:05 | | |
| | | Last Modification Time: | | |
| | | Page number: 53 | | |
| EXPIRED CARBON MONOXIDE | | | | |
| Actual Time | ECO Level (ppm) | %COHb | Comments | |

| | | | | |
|--------------------------|-------------------------|---------------------------------|------------------|---------------------------|
| Section: Vital | | 3 of 5 | Blank? Y | Section Status: Created |
| Visit: WEEK 22 | | Section Date: 01-01-2001 | | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:55:05 | | |
| | | Last Modification Time: | | |
| | | Page number: 53 | | |
| VITAL SIGNS | | | | |
| Actual Time | Blood Pressure | Pulse | Respiratory Rate | Oral Temperature xxx.x |
| | Systolic Diastolic | | | Unit |
| Comments | | | | |

| | | | | |
|---------------------------|--|---------------------------------|----------|-------------------------|
| Section: Unused_Study_Pro | | 4 of 5 | Blank? Y | Section Status: Created |
| Visit: WEEK 22 | | Section Date: 01-01-2001 | | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:55:05 | | |
| | | Last Modification Time: | | |

CRF Report for Study E6270229

Patient: 3026
CRF: Week 22
Visit: WEEK 22

Site: CDB_001
Blank? Y
Visit Date: 01-01-2001

Investigator: CDB_001
CRF Page #: 22
Document #: R169152413

| | | | | | |
|-------------------------------|--|--------|--|-----------------|---------------------------------|
| 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: 01-01-2001 | | | |
| Entered By: Melissa Zeis | | | | Entry Time: 07-12-2007 18:55:05 | | | |
| | | | | Last Modification Time: | | | |
| | | | | Page number: 54 | | | |
| STUDY PRODUCT DISPENSATION | | | | | | | |
| Actual Time | | Product Dispensed | | Flavor | | Amount Dispensed | |

CRF Report for Study E6270229

Patient: 3026
CRF: Week 24 (Eos)
Visit: WEEK 24 (EOS)

Site: CDB_001
Blank? Y
Visit Date: 01-01-2001
Entry Time: 07-12-2007 18:55:13
Modification Time:
Approval Time:
Verification Time:

Investigator: CDB_001
CRF Page #: 23
Document #: R169152513
CRF Status: Created

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

Approver:
Verifier:

| | | | |
|---------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|-------------------------|
| Section: Pro_Questionnair | 1 of 12 | Blank? Y | Section Status: Created |
| Visit: WEEK 24 (EOS) | | Section Date: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:55:13 | |
| | | 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: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:55:13 | |
| | | 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: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:55:13 | |
| | | 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: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:55:13 | |
| | | Last Modification Time: | |
| | | Page number: 55 | |
| Pregnancy Test | | | |

CRF Report for Study E6270229

Patient: 3026

CRF: Week 24 (Eos)

Visit: WEEK 24 (EOS)

Site: CDB_001

Blank? Y

Visit Date: 01-01-2001

Investigator: CDB_001

CRF Page #: 23

Document #: R169152513

| | |
|--------------------|---------|
| 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: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:55:13 | |
| | | 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: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:55:13 | |
| | | Last Modification Time: | |
| | | Page number: 56 | |
| 12-LEAD ELECTROCARDIOGRAM REPORT | | | |
| Actual Time | Ventricular Heart Rate | | |
| | Cardiac Cycle Measurements | | |
| PR Interval | QRS Duration | QT Interval | QTc Interval |
| ECG INTERPRETATION: | | | |
| Comments (related to abnormal, CS findings only): | | | |

| | | | |
|---------------------------------------|-------------|---------------------------------|----------------------------------|
| Section: Hdyl Oral Health | 7 of 12 | Blank? Y | Section Status: Created |
| Visit: WEEK 24 (EOS) | | Section Date: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:55:13 | |
| | | 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: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:55:13 | |
| | | Last Modification Time: | |

CRF Report for Study E6270229



Patient: 3026
CRF: Week 24 (Eos)
Visit: WEEK 24 (EOS)

Site: CDB_001
Blank? Y
Visit Date: 01-01-2001

Investigator: CDB_001
CRF Page #: 23
Document #: R169152513

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

| | | | | | | | |
|---------------------------|-----------|---------------------------------|--|---------------------|--|-------------------------|--|
| Section: Oral_Health_Exam | | 9 of 12 | | Blank? Y | | Section Status: Created | |
| Visit: WEEK 24 (EOS) | | Section Date: 01-01-2001 | | | | | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:55:13 | | | | | |
| | | 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: 01-01-2001 | | | | | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:55:13 | | | | | |
| | | 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: 01-01-2001 | | | | | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:55:13 | | | | | |
| | | Last Modification Time: | | | | | |
| | | Page number: 58 | | | | | |
| WEIGHT & HEIGHT | | | | | | | |
| Date | Weight | Unit | Height | Unit | | | |
| | xxx.x | | xxx.x | | | | |

| | | | | | | | |
|--------------------------|--|---------------------------------|--|----------|--|-------------------------|--|
| Section: Lab_Eval | | 12 of 12 | | Blank? Y | | Section Status: Created | |
| Visit: WEEK 24 (EOS) | | Section Date: 01-01-2001 | | | | | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:55:13 | | | | | |

CRF Report for Study E6270229

Patient: 3026

CRF: Week 24 (Eos)

Visit: WEEK 24 (EOS)

Site: CDB_001

Blank? Y

Visit Date: 01-01-2001

Investigator: CDB_001

CRF Page #: 23

Document #: R169152513

Section: Lab_Eval

12 of 12

Last Modification Time:

Page number: 59

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

No, specify

Requisition Number 1

Requisition Number 2 (if applicable)

Were there any clinically significant labs?

(Yes, specify below)

Requisition Number

Test Name

H/L

Lab ID

Lab Name

CRF Report for Study E6270229



Patient: 3026

CRF: Week 24-2 (Eos)

Visit: WEEK 24 (EOS)

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? Y

Visit Date: 01-01-2001

Entry Time: 07-12-2007 18:55:21

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 24

Document #: R169152613

CRF Status: Created

Approver:

Verifier:

| Section: Pk_Blood_Biomark | 1 of 11 | Blank? Y | Section Status: Created | | | | | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|---------------------------------|-------------------------|------|-------------|----------|--|--|--|
| Visit: WEEK 24 (EOS) | | Section Date: 01-01-2001 | | | | | | | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:55:21 | | | | | | | |
| | | Last Modification Time: | | | | | | | |
| | | Page number: 59 | | | | | | | |
| <p>Blood Sampling For Biomarkers/Chemistry/Hematology (following an overnight fast)</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 15%;">Date</th> <th style="width: 15%;">Actual Time</th> <th style="width: 70%;">Comments</th> </tr> </thead> <tbody> <tr> <td colspan="3" style="height: 40px;"> </td> </tr> </tbody> </table> | | | | Date | Actual Time | Comments | | | |
| Date | Actual Time | Comments | | | | | | | |
| | | | | | | | | | |

| Section: Expired_Carbon_M | 2 of 11 | Blank? Y | Section Status: Created | | | | | | | | | | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|---------------------------------|-------------------------|----------|-------------|-----------------|-------|----------|--|--|--|--|--|
| Visit: WEEK 24 (EOS) | | Section Date: 01-01-2001 | | | | | | | | | | | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:55:21 | | | | | | | | | | | |
| | | Last Modification Time: | | | | | | | | | | | |
| | | Page number: 59 | | | | | | | | | | | |
| <p>EXPIRED CARBON MONOXIDE</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 15%;">Date</th> <th style="width: 15%;">Actual Time</th> <th style="width: 20%;">ECO Level (ppm)</th> <th style="width: 15%;">%COHb</th> <th style="width: 35%;">Comments</th> </tr> </thead> <tbody> <tr> <td colspan="5" style="height: 40px;"> </td> </tr> </tbody> </table> | | | | Date | Actual Time | ECO Level (ppm) | %COHb | Comments | | | | | |
| 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: 01-01-2001 | | | | | | | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:55:21 | | | | | | | |
| | | Last Modification Time: | | | | | | | |
| | | Page number: 59 | | | | | | | |
| <p>Blood Sampling for %COHb</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 15%;">Date</th> <th style="width: 15%;">Actual Time</th> <th style="width: 70%;">Comments</th> </tr> </thead> <tbody> <tr> <td colspan="3" style="height: 40px;"> </td> </tr> </tbody> </table> | | | | Date | Actual Time | Comments | | | |
| Date | Actual Time | Comments | | | | | | | |
| | | | | | | | | | |

| Section: Pre_Bronch_Spir | 4 of 11 | Blank? Y | Section Status: Created | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|---------------------------------|-------------------------|-------------|--|
| Visit: WEEK 24 (EOS) | | Section Date: 01-01-2001 | | | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:55:21 | | | |
| | | Last Modification Time: | | | |
| | | Page number: 60 | | | |
| <p>PRE-BRONCHODILATOR BEST BASELINE SPIROMETRY TEST RESULT</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 100%;">Actual Time</th> </tr> </thead> <tbody> <tr> <td style="height: 40px;"> </td> </tr> </tbody> </table> | | | | Actual Time | |
| Actual Time | | | | | |
| | | | | | |

CRF Report for Study E6270229

Patient: 3026

CRF: Week 24-2 (Eos)

Visit: WEEK 24 (EOS)

Site: CDB_001

Blank? Y

Visit Date: 01-01-2001

Investigator: CDB_001

CRF Page #: 24

Document #: R169152613

| | | | | | | | |
|--------------------------|---------------------|---------------------|--------|--------------------|-------|----------------------|----------|
| 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: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:55:21 | |
| | 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: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:55:21 | |
| | Last Modification Time: | | |
| | Page number: 60 | | |
| POST-BRONCHODILATOR BEST SPIROMETRY TEST RESULT | | | |
| | Actual Time of FEV1/FVC | Testing Position | |
| Date | Test | FEV1 L | FEV1 Predicted (%) |
| | | FVC L | FVC Predicted (%) |
| | | | Comments |

| | | | | | | | | | |
|-------------------------------------------------|--|------------|--|---------------------------------|--|-------------------------|--|--------------------|--|
| Section: Used Study Tobac | | 7 of 11 | | Blank? Y | | Section Status: Created | | | |
| Visit: WEEK 24 (EOS) | | | | Section Date: 01-01-2001 | | | | | |
| Entered By: Melissa Zeis | | | | Entry Time: 07-12-2007 18:55:21 | | | | | |
| | | | | Last Modification Time: | | | | | |
| | | | | Page number: 61 | | | | | |
| USED STUDY TOBACCO-HEATING CIGARETTE COLLECTION | | | | | | | | | |
| Scheduled Collection | | | | Number of Study | | Weight of | | | |
| | | | | Tobacco-Heating | | Cigarettes Collected | | Any Product | |
| Timepoint | | Start Date | | Stop | | (g) | | Deviation? | |
| | | Start Time | | Date | | | | If yes, # of other | |
| | | | | Time | | | | Brand | |
| | | | | | | | | Comments | |

| | | | |
|--------------------------|---------|---------------------------------|-------------------------|
| Section: Used_Study_Snus | 8 of 11 | Blank? Y | Section Status: Created |
| Visit: WEEK 24 (EOS) | | Section Date: 01-01-2001 | |
| Entered By: Melissa Zeis | | Entry Time: 07-12-2007 18:55:21 | |

CRF Report for Study E6270229

Patient: 3026

CRF: Week 24-2 (Eos)

Visit: WEEK 24 (EOS)

Site: CDB_001

Blank? Y

Visit Date: 01-01-2001

Investigator: CDB_001

CRF Page #: 24

Document #: R169152613

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: 01-01-2001

Entered By: Melissa Zeis

Entry Time: 07-12-2007 18:55:21

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: 01-01-2001

Entered By: Melissa Zeis

Entry Time: 07-12-2007 18:55:21

Last Modification Time:

Page number: 64

USUAL STUDY TOBACCO-BURNING CIGARETTE BUTT MEASUREMENT

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

Section: Used_Butt_Measur 11 of 11

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 01-01-2001

Entered By: Melissa Zeis

Entry Time: 07-12-2007 18:55:21

Last Modification Time:

Page number: 65

USED STUDY TOBACCO-BURNING CIGARETTE BUTT MEASUREMENT

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

CRF Report for Study E6270229



Patient: 3026

CRF: Week 24-3

Visit: WEEK 24 (EOS)

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? Y

Visit Date: 01-01-2001

Entry Time: 07-12-2007 18:55:31

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 25

Document #: R169152713

CRF Status: Created

Approver:

Verifier:

Section: Unused_Study_Pro

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 01-01-2001

Entered By: Melissa Zeis

Entry Time: 07-12-2007 18:55:31

Last Modification Time:

Page number: 65A

Unused Study Product Returned

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

CRF Report for Study E6270229



Patient: 3026

CRF: Precon_Med

Visit: PRECON_MEDS

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? N

Visit Date: 03-05-2007

Entry Time: 07-12-2007 18:55:38

Modification Time: 10-12-2007 09:44:09

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 26

Document #: R169152813

CRF Status: Entry Complete

Approver:

Verifier:

Section: Pre_Conmed

Blank? N

Section Status: Entry Complete

Visit: PRECON_MEDS

Section Date: 03-05-2007

Entered By: Melissa Zeis

Entry Time: 07-12-2007 18:55:38

Last Modification Time: 07-12-2007 18:58:33

Page number: 66

Previous and Concomitant Medications

Has the subject taken any medications prior to the first use of study product and/or during the study as restricted by the protocol?

YES

| Seq # | Drug Name | Indication | Dose / Dose Unit | Route | Specify | Freq | Specify | Start Date | Stop Date/Ongoing |
|-------|-----------|------------|---------------------|-------|---------|------|---------|------------|-------------------|
| 1 | ALEVE | HEADACHE | 1 | PO | TAB | PRN | | 00-00-1977 | 00-00-2007 |

CRF Report for Study E6270229



Patient: 3026

CRF: AE

Visit: AE

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? N

Visit Date: 24-05-2007

Entry Time: 07-12-2007 18:58:35

Modification Time: 09-12-2007 13:36:53

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 27

Document #: R169152913

CRF Status: Entry Complete

Approver:

Verifier:

Section: Ae_Med

Blank? N

Section Status: Entry Complete

Visit: AE

Section Date: 24-05-2007

Entered By: Melissa Zeis

Entry Time: 07-12-2007 18:58:35

Last Modification Time: 09-12-2007 13:36:53

Page number: 67

Adverse Events

Did the subject experience any adverse events?

NO

Onset

Resolved/Changed

Serious

Relationship to

Procedure

Action

Outcome

Event No.

Adverse Event

Date

Time

Date

Time

Event?

Severity

Product

Taken

to Date

CRF Report for Study E6270229



Patient: 3026

CRF: Ecg_Unscheduled

Visit: ECG_UNSCHE

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? Y

Visit Date: 00-00-

Entry Time: 07-12-2007 18:58:43

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 28

Document #: R169153013

CRF Status: Created

Approver:

Verifier:

Section: ECG

Blank? Y

Section Status: Created

Visit: ECG_UNSCHE

Section Date: 00-00-

Entered By: Melissa Zeis

Entry Time: 07-12-2007 18:58:43

Last Modification Time:

Page number: 68

UNSCHEDULED 12-LEAD ELECTROCARDIOGRAM REPORT

Ventricular

Cardiac Cycle Measurements

| Date | Actual Time | Heart Rate | PR Interval | QRS Duration | QT Interval | QTc Interval | Interpretation | Comments |
|------|-------------|------------|-------------|--------------|-------------|--------------|----------------|----------|
|------|-------------|------------|-------------|--------------|-------------|--------------|----------------|----------|

CRF Report for Study E6270229



Patient: 3026

CRF: Lab_Unscheduled

Visit: LAB_UNSCHE

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? Y

Visit Date: 00-00-

Entry Time: 07-12-2007 18:58:47

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 29

Document #: R169153113

CRF Status: Created

Approver:

Verifier:

Section: Lab_Eval

Blank? Y

Section Status: Created

Visit: LAB_UNSCHE

Section Date: 00-00-

Entered By: Melissa Zeis

Entry Time: 07-12-2007 18:58:47

Last Modification Time:

Page number: 69

Unscheduled Laboratory Evaluations

Clinically

If Clinically Significant, Specify

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

CRF Report for Study E6270229

Patient: 3026

CRF: Vital_Unscheduled

Visit: VITAL_UNSCHEDED

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? Y

Visit Date: 00-00-

Entry Time: 07-12-2007 18:58:52

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 30

Document #: R169153213

CRF Status: Created

Approver:

Verifier:

Section: Vital

Blank? Y

Section Status: Created

Visit: VITAL_UNSCHEDED

Section Date: 00-00-

Entered By: Melissa Zeis

Entry Time: 07-12-2007 18:58:52

Last Modification Time:

Page number: 70

UNSCHEDULED VITAL SIGNS

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

CRF Report for Study E6270229



Patient: 3026

Site: CDB_001

Investigator: CDB_001

CRF: Stdy_Prdt_Dis_Unschedule

Blank? Y

CRF Page #: 31

Visit: STDY_PRDT_UNSCHE

Visit Date: 00-00-

Document #: R169153313

Entered By: Melissa Zeis

Entry Time: 07-12-2007 18:58:56

CRF Status: Created

Discrepancies: None

Modification Time:

Approval Status: Not Approved

Approval Time:

Approver:

Verification: Not Verified

Verification Time:

Verifier:

Comment:

Section: Study_Prod_Dispe

Blank? Y

Section Status: Created

Visit: STDY_PRDT_UNSCHE

Section Date: 00-00-

Entered By: Melissa Zeis

Entry Time: 07-12-2007 18:58:56

Last Modification Time:

Page number: 71

UNSCHEDULED STUDY PRODUCT DISPENSATION

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

CRF Report for Study E6270229



Patient: 3026

Site: CDB_001

Investigator: CDB_001

CRF: Expired_Co2_Unscheduled

Blank? Y

CRF Page #: 32

Visit: EXPIRED_CO2_UNSC

Visit Date: 00-00-

Document #: R169153413

Entered By: Melissa Zeis

Entry Time: 07-12-2007 18:59:00

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: 00-00-

Entered By: Melissa Zeis

Entry Time: 07-12-2007 18:59:00

Last Modification Time:

Page number: 72

UNSCHEDULED EXPIRED CARBON MONOXIDE

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

CRF Report for Study E6270229



Patient: 3026

CRF: Oral_Health_Unscheduled

Visit: ORAL_HEALTH_UNSC

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? Y

Visit Date: 00-00-

Entry Time: 07-12-2007 18:59:04

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 33

Document #: R169153513

CRF Status: Created

Approver:

Verifier:

Section: Oral_Health_Exam

Blank? Y

Section Status: Created

Visit: ORAL_HEALTH_UNSC

Section Date: 00-00-

Entered By: Melissa Zeis

Entry Time: 07-12-2007 18:59:04

Last Modification Time:

Page number: 73

UNSCHEDULED ORAL HEALTH EXAMINATION

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

CRF Report for Study E6270229



Patient: 3026

CRF: Spirometry_Unscheduled

Visit: SPIRO_TEST_UNSCH

Site: CDB_001

Blank? Y

Visit Date: 00-00-

Investigator: CDB_001

CRF Page #: 34

Document #: R169153613

Entered By: Melissa Zeis

Entry Time: 07-12-2007 18:59:09

CRF Status: Created

Discrepancies: None

Modification Time:

Approval Status: Not Approved

Approval Time:

Verification: Not Verified

Verification Time:

Approver:

Verifier:

Comment:

Section: Pre_Bronch_Spir

Blank? Y

Section Status: Created

Visit: SPIRO_TEST_UNSCH

Section Date: 00-00-

Entered By: Melissa Zeis

Entry Time: 07-12-2007 18:59:09

Last Modification Time:

Page number: 74

UNSCHEDULED SPIROMETRY TEST RESULT

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

CRF Report for Study E6270229



Patient: 3026

CRF: Study_Completion

Visit: STUDY_COMP

Entered By: Melissa Zeis

Discrepancies: Active

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? N

Visit Date: 24-05-2007

Entry Time: 07-12-2007 18:59:13

Modification Time: 10-12-2007 09:44:40

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 35

Document #: R169153713

CRF Status: Entry Complete

Approver:

Verifier:

Section: Study_Comp

Blank? N

Section Status: Entry Complete

Visit: STUDY_COMP

Section Date: 24-05-2007

Entered By: Melissa Zeis

Entry Time: 07-12-2007 18:59:13

Last Modification Time: 07-12-2007 19:01:33

Page number: 75

Study Completion

Did the subject complete the study?

NO

Date the subject completed OR withdrew from the study:

24-05-2007

Reason for Withdrawal

CONSENT

Specify

SUBJECT DID NOT WANT TO USE SNUS

Investigator Comments

Principal Investigator

Date

17 DEC 2007

Covance CLS

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

LABORATORY REPORT

ACCESSION NO. N746086

Page 1 of 3

INVESTIGATOR: (B17177)

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

SPONSOR REPORT TO:

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

PROTOCOL 6270-229

INVESTIGATOR NO.: 3

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME: 10:37 DATE: 03-May-2007

DATE RECEIVED IN LABORATORY: 04-May-2007

DATE REPORTED BY LABORATORY: 07-May-2007

SEX: F BIRTHDATE: (b) (6) AGE: 46

SCREENING NUMBER: S3072

Is this Clinically
Significant/ Adverse
Event?

Yes

No

SCREEN CHEMISTRY PANEL

| | | | |
|------------|-----|---|----------------|
| Total Bili | 0.3 | | 0.2-1.2 mg/dL |
| Alk Phos | 69 | | 31-106 U/L |
| ALT (SGPT) | 36 | H | 6-34 U/L |
| AST (SGOT) | 28 | | 9-34 U/L |
| GGT | 64 | H | 4-49 U/L |
| LDH | 151 | | 53-234 U/L |
| Urea Nitr | 16 | | 4-24 mg/dL |
| Creatinine | 0.8 | | 0.4-1.1 mg/dL |
| Glucose | 90 | | 70-115 mg/dL |
| Uric Acid | 6.9 | | 2.1-7.2 mg/dL |
| Calcium | 9.4 | | 8.3-10.6 mg/dL |
| Phosphorus | 3.2 | | 2.2-5.1 mg/dL |
| Total Prot | 6.7 | | 6.1-8.4 g/dL |
| Albumin | 4.0 | | 3.3-4.9 g/dL |
| Sodium | 141 | | 132-147 mEq/L |
| Potassium | 4.6 | | 3.4-5.4 mEq/L |
| Chloride | 105 | | 94-112 mEq/L |
| Triglycer | 153 | | 45-214 mg/dL |
| Cholest | 184 | | 155-265 mg/dL |

P2
8 May 2007

Investigator Signature:

08 MAY 2007
Date:

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

Ac'd KY 22 May 2007
B17177
(INV)

Covance CLS

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LABORATORY REPORT

ACCESSION NO. N746086

Page 2 of 3

INVESTIGATOR: (B17177)

Frank Farmer, Jr., M.D.

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1900 Mason Ave

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Medical Director

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3402 Kinsman Boulevard

Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 3

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME: 10:37 DATE: 03-May-2007

DATE RECEIVED IN LABORATORY: 04-May-2007

DATE REPORTED BY LABORATORY: 07-May-2007

SEX: F BIRTHDATE: (b) (6) AGE: 46

SCREENING NUMBER: S3072

Is this Clinically
Significant/ Adverse
Event?

Yes

No

HEMATOLOGY& DIFFERENTIAL PANEL

| | | |
|------------|------------|---------------------------------|
| HGB | 15.4 | 11.6-16.4 g/dL |
| HCT | 46 | 34-48 % |
| RBC | 5.5 | 4.1-5.6x10 ⁶ /uL |
| MCV | 83 | 79-98 fL |
| MCH | 28 | 26-34 pg |
| MCHC | 34 | 31-38 g/dL |
| RDW | 13.3 | 12.0-15.0 % |
| RBC Morph | Normocytic | |
| WBC | 5.67 | 3.80-10.70 x10 ³ /uL |
| Neutrophil | 2.82 | 1.96-7.23 x10 ³ /uL |
| Lymphocyte | 2.46 | 0.91-4.28 x10 ³ /uL |
| Monocytes | 0.31 | 0.12-0.92 x10 ³ /uL |
| Eosinophil | 0.06 | 0.00-0.57 x10 ³ /uL |
| Basophils | 0.02 | 0.00-0.20 x10 ³ /uL |
| Neutrophil | 49.8 | 40.5-75.0 % |
| Lymphocyte | 43.3 | 15.4-48.5 % |
| Monocytes | 5.4 | 2.6-10.1 % |
| Eosinophil | 1.1 | 0.0-6.8 % |
| Basophils | 0.3 | 0.0-2.0 % |
| Platelets | 178 | 140-400 x10 ³ /uL |

Summary 2007

Investigator Signature:

08 MAY 2007
Date:

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

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Qcd KH 22 May 2007 (INV)

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LABORATORY REPORT

ACCESSION NO. N746086

Page 3 of 3

INVESTIGATOR: (B17177)

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PROTOCOL 6270-229

INVESTIGATOR NO.: 3

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

SPONSOR REPORT TO:

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

Screen

COLLECTION TIME: 10:37 DATE: 03-May-2007

DATE RECEIVED IN LABORATORY: 04-May-2007

DATE REPORTED BY LABORATORY: 07-May-2007

SEX: F BIRTHDATE: (b) (6) AGE: 46

SCREENING NUMBER: S3072

Is this Clinically
Significant/ Adverse
Event?

Yes

No

URINE MACRO & MICRO PANEL

| | | |
|-----------|----------|---------------------------------|
| Color | Yellow | Ref Rng: Colorless or Yellow |
| Clarity | Clear | Ref Rng: Clear |
| Spec Grav | 1.026 | 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 | Positive | |

8 May 2007

CELLULAR ELEMENTS

| | | |
|-----------|---|-----------|
| RBC | 1 | 0-8 /HPF |
| WBC | 1 | 0-12 /HPF |
| Squam Epi | 3 | 0-3 /HPF |

MISCELLANEOUS ELEMENTS

Mucous Present Ref Rng: Not present

*WCS
8 May 2007*

Investigator Signature:

08 MAY 2007
Date:

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

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Qcd KH 22 May 2007 (INV)

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LABORATORY REPORT

ACCESSION NO. N746086

Page 1 of 1

INVESTIGATOR: (B17177)

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Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 3

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME: 10:37 DATE: 03-May-2007

DATE RECEIVED IN LABORATORY: 04-May-2007

DATE REPORTED BY LABORATORY: 07-May-2007

SEX: F BIRTHDATE: (b) (6) AGE: 46

SCREENING NUMBER: S3072

Is this Clinically
Significant/ Adverse
Event?

Yes

No

TOTAL IRON

Total Iron 69 30-160 ug/dL

FOLLICLE STIMULATING HORMONE

FSH 69.7

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

8 May 2007

HEPATITIS A ANTIBODY-IGM

HepA IgM Ab Negative No Ref Rng

Jul Lee
Investigator Signature:

08 MAY 2007
Date:

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

B17177

(INV)

Qcd K1122 May 2007

Covance CLS

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LABORATORY REPORT

ACCESSION NO. N746086

Page 1 of 1

INVESTIGATOR: (B17177)

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SPONSOR REPORT TO:

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Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 3

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME: 10:37 DATE: 03-May-2007

DATE RECEIVED IN LABORATORY: 04-May-2007

DATE REPORTED BY LABORATORY: 07-May-2007

SEX: F BIRTHDATE: (b) (6) AGE: 46

SCREENING NUMBER: S3072

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

5.8

pg/mL

See Inv. Manual

Summary
8 May 2007


Investigator Signature:

08 MAY 2007
Date:

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

B17177

Did KH 22 May 2007 (INV)

Covance CLS

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LABORATORY REPORT

ACCESSION NO. N746086

Page 1 of 1

INVESTIGATOR: (B17177)

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Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 3

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME: 10:37 DATE: 03-May-2007

DATE RECEIVED IN LABORATORY: 04-May-2007

DATE REPORTED BY LABORATORY: 07-May-2007

SEX: F BIRTHDATE: (b) (6) AGE: 46

SCREENING NUMBER: S3072

Is this Clinically
Significant/ Adverse
Event?

Yes

No

HIV 1/HIV 2 ANTIBODY SCREEN

HIV-1/2

Non-Reactive

Reference Range:

Non-Reactive

Summer 2007

Jul J...
Investigator Signature:

08 MAY 2007
Date:

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

B17177

Oct 14 2007 (INV)

Covance CLS

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LABORATORY REPORT

ACCESSION NO. N746086

Page 1 of 1

INVESTIGATOR: (B17177)

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

PROTOCOL 6270-229

INVESTIGATOR NO.: 3

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME: 10:37 DATE: 03-May-2007

DATE RECEIVED IN LABORATORY: 04-May-2007

DATE REPORTED BY LABORATORY: 07-May-2007

SEX: F BIRTHDATE: (b) (6) AGE: 46

SCREENING NUMBER: S3072

Is this Clinically
Significant/ Adverse
Event?

Yes

No

HEPATITIS B CORE ANTIBODY-IGM

Hep Bc IgM

Negative

Ref Rng: Negative

8 May run

[Signature]
Investigator Signature:

08 MAY 2007

08 MAY 2007
Date:

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

B17177

Did HA 22 May 2007

(INV)

Covance CLS

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Tel. +1 (800) 327 7270
LABORATORY REPORT

ACCESSION NO. N746086

Page 1 of 1

INVESTIGATOR: (B17177)

Frank Farmer, Jr., M.D.
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1900 Mason Ave
Daytona Beach, FL 32117

SPONSOR REPORT TO:

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

PROTOCOL 6270-229

INVESTIGATOR NO.: 3

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME: 10:37 DATE: 03-May-2007

DATE RECEIVED IN LABORATORY: 04-May-2007

DATE REPORTED BY LABORATORY: 07-May-2007

SEX: F BIRTHDATE: (b) (6) AGE: 46

SCREENING NUMBER: S3072

Is this Clinically
Significant/ Adverse
Event?

Yes

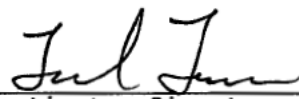
No

HAS PATIENT FASTED 8 HOURS?

Fasted? Yes

IS SUBJECT A SMOKER OR NON-SM?

smoker/non Smoker

8-May-2007

Investigator Signature:

08 MAY 2007
Date:

B17177

(INV)

Covance CLS

QcdKH 22 May 2007

Covance CLS

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

ACCESSION NO. P205166

Page 1 of 1

INVESTIGATOR: (B17177)

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Daytona Beach, FL 32117

SPONSOR REPORT TO:

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

PROTOCOL 6270-229

INVESTIGATOR NO.: 3

RANDOMIZATION NUMBER: R3026

PATIENT INITIALS: (b) (6)

VISIT: 24 HR UR

24 Hr Urine Collection

COLLECTION TIME: 17:21 DATE: 23-May-2007

DATE RECEIVED IN LABORATORY: 26-May-2007

DATE REPORTED BY LABORATORY: 26-May-2007

SEX: F BIRTHDATE: (b) (6) AGE: 46

SCREENING NUMBER: S3072

Is this Clinically
Significant/ Adverse
Event?

Yes

No

URINE CREATININE, 24 HR

U24h Creat 1402

UA1q24Crea 93.6

600-1600 mg/24hr

mg/dL No Ref Rng

ELAPSED DATE AND TIME, 24HR

Elpsd D&T 1394

min

24 HR COLLECTION INFORMATION

Start Date 23-May-2007

Start Time 17:21

Stop Date 24-May-2007

Stop Time 16:35

24 May 2007

TOTAL 24HR URINE VOLUME

Total Vol. 1450

mL

J. J.
Investigator Signature:

30 May 2007
Date:

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

B17177

(INV)

QC DO
06-Jun-2007

Covance CLS

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Tel. +1 (800) 327 7270
LABORATORY REPORT

ACCESSION NO. P060625

Page 1 of 1

INVESTIGATOR: (B20476)

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

SPONSOR REPORT TO:

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

PROTOCOL 6270-229

INVESTIGATOR NO.: 3

RANDOMIZATION NUMBER: R3026

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 06:41 DATE: 24-May-2007

DATE RECEIVED IN LABORATORY: 25-May-2007

DATE REPORTED BY LABORATORY: 15-Jun-2007

SEX: F BIRTHDATE: (b) (6) AGE: 46

SCREENING NUMBER: S3072

Is this Clinically
Significant/ Adverse
Event?

Yes

No

sICAM-1

sICAM-1

303

115-306 ng/mL

18 Jun 2007

[Signature]
Investigator Signature:

18 JUN 2007
Date:

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

B20476

(INV)

Covance CLS

Marietta Henry, M.D., Director
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LABORATORY REPORT

ACCESSION NO. P060625

Page 1 of 1

INVESTIGATOR: (B17177)

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1900 Mason Ave
Daytona Beach, FL 32117

SPONSOR REPORT TO:

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

PROTOCOL 6270-229

INVESTIGATOR NO.: 3

RANDOMIZATION NUMBER: R3026

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 06:41 DATE: 24-May-2007

DATE RECEIVED IN LABORATORY: 25-May-2007

DATE REPORTED BY LABORATORY: 26-May-2007

SEX: F BIRTHDATE: (b) (6) AGE: 46

SCREENING NUMBER: S3072

Is this Clinically
Significant/ Adverse
Event?

Yes

No

LIPID PANEL

| | | | |
|-----------|-----|---|---------------|
| Triglycer | 336 | H | 45-214 mg/dL |
| Cholest | 172 | | 155-265 mg/dL |
| HDL Dex-S | 35 | | 34-87 mg/dL |
| LDL Chol | 70 | L | 79-186 mg/dL |

[]

[]

[]

[]

[Signature]
24 May 2007

[Signature]
Investigator Signature:

30 May 2007
Date:

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

B17177

SC 70
06 Jun 2007

(INV)

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LABORATORY REPORT

ACCESSION NO. P060625

Page 1 of 1

INVESTIGATOR: (B17177)

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Daytona Beach, FL 32117

SPONSOR REPORT TO:

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

PROTOCOL 6270-229

INVESTIGATOR NO.: 3

RANDOMIZATION NUMBER: R3026

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 06:41 DATE: 24-May-2007

DATE RECEIVED IN LABORATORY: 25-May-2007

DATE REPORTED BY LABORATORY: 26-May-2007

SEX: F BIRTHDATE: (b) (6) AGE: 46

SCREENING NUMBER: S3072

Is this Clinically
Significant/ Adverse
Event?

Yes

No

HOMOCYSTEINE

*1 HCY

7.36

3.36-20.44 umol/L

Handwritten signature
29 May 2007

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

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Investigator Signature:

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Date:

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

B17177

(INV)

Handwritten signature
06-Jun-2007

Covance CLS

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

LABORATORY REPORT

ACCESSION NO. P060625

Page 1 of 1

INVESTIGATOR: (B17177)

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

SPONSOR REPORT TO:

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

PROTOCOL 6270-229

INVESTIGATOR NO.: 3

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

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SCREENING NUMBER: S3072

Is this Clinically
Significant/ Adverse
Event?

Yes

No

RBC CELL WASHING (4-ABP-HB)

Wash/Store Completed

Handwritten signature
24 May 2007

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Investigator Signature:

Handwritten date
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(INV)

Handwritten date
30 MAY 2007
QC 30
06-Jun-2007

Covance CLS

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Event?

Yes

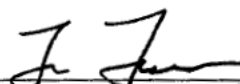
No

CHEMISTRY PANEL

| | | |
|------------|-----|----------------|
| Total Bili | 0.2 | 0.2-1.2 mg/dL |
| Alk Phos | 70 | 31-106 U/L |
| ALT (SGPT) | 31 | 6-34 U/L |
| AST (SGOT) | 26 | 9-34 U/L |
| GGT | 60 | 4-49 U/L |
| LDH | 158 | 53-234 U/L |
| Urea Nitr | 11 | 4-24 mg/dL |
| Creatinine | 0.9 | 0.4-1.1 mg/dL |
| Glucose | 100 | 70-115 mg/dL |
| Uric Acid | 6.5 | 2.1-7.2 mg/dL |
| Calcium | 9.4 | 8.3-10.6 mg/dL |
| Phosphorus | 4.0 | 2.2-5.1 mg/dL |
| Total Prot | 6.5 | 6.1-8.4 g/dL |
| Albumin | 4.0 | 3.3-4.9 g/dL |
| Sodium | 141 | 132-147 mEq/L |
| Potassium | 4.5 | 3.4-5.4 mEq/L |
| Chloride | 104 | 94-112 mEq/L |

[]

[]

25 May 2007

Investigator Signature:

30 May 2007
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06 Jun 2007

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Event?

Yes

No

HEMATOLOGY & DIFFERENTIAL PANEL

| | | |
|------------|------------|---------------------------------|
| HGB | 15.4 | 11.6-16.4 g/dL |
| HCT | 47 | 34-48 % |
| RBC | 5.4 | 4.1-5.6x10 ⁶ /uL |
| MCV | 87 | 79-98 fL |
| MCH | 28 | 26-34 pg |
| MCHC | 33 | 31-38 g/dL |
| RDW | 13.3 | 12.0-15.0 % |
| RBC Morph | Normocytic | |
| WBC | 5.42 | 3.80-10.70 x10 ³ /uL |
| Neutrophil | 2.52 | 1.96-7.23 x10 ³ /uL |
| Lymphocyte | 2.41 | 0.91-4.28 x10 ³ /uL |
| Monocytes | 0.40 | 0.12-0.92 x10 ³ /uL |
| Eosinophil | 0.07 | 0.00-0.57 x10 ³ /uL |
| Basophils | 0.02 | 0.00-0.20 x10 ³ /uL |
| Neutrophil | 46.4 | 40.5-75.0 % |
| Lymphocyte | 44.5 | 15.4-48.5 % |
| Monocytes | 7.4 | 2.6-10.1 % |
| Eosinophil | 1.3 | 0.0-6.8 % |
| Basophils | 0.4 | 0.0-2.0 % |
| Platelets | 202 | 140-400 x10 ³ /uL |

R
24 May 2007

F. Farmer
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30 May 2007
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Is this Clinically
Significant/ Adverse
Event?

Yes

No

URINE MACRO & MICRO PANEL

| | |
|-----------|----------|
| Color | Yellow |
| Clarity | Clear |
| Spec Grav | 1.020 |
| pH | 5.5 |
| Protein | Negative |
| Glucose | Normal |
| Ketones | Negative |
| Bilirubin | Negative |
| Urobilin | Normal |
| Blood | Negative |
| Nitrite | Negative |
| Leuk Est | Negative |
| Microscop | Positive |

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

Pr
24 May 2007

CELLULAR ELEMENTS

| | | |
|-----------|---|----------|
| Squam Epi | 3 | 0-3 /HPF |
|-----------|---|----------|

MISCELLANEOUS ELEMENTS

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

NCS

[Signature]
Investigator Signature:

30 May 2007
Date:

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QC DJ
06-MAY 06-JUN 2007
JUN-2007

Covance CLS

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Is this Clinically
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Event?

Yes

No

TOTAL IRON

Total Iron 77 30-160 ug/dL

C-REACTIVE PROTEIN

CRP-HS 0.138 <=0.287 mg/dL

CARBOXYHEMOGLOBIN

Carboxyhem 5.4 % saturation
No Ref Rng

29 May 2007

J. Farmer
Investigator Signature:

30 May 2007
Date:

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*QC 79
on 5 Jun 2007*

Covance CLS

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Is this Clinically
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Yes

No

FIBRINOGEN

Fibrinogen 246 200-400 mg/dL

R
28 May 2007

J. Farmer
Investigator Signature:

30 May 2007
Date:

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AC DO DO
06-Jun-06 Jan 2007

Covance CLS

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

ACCESSION NO. P060625

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PROTOCOL 6270-229

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Is this Clinically
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Event?

Yes

No

URINE CREATININE, SPOT

Rnd Ur Crt 127

mg/dL No Ref Rng

Handwritten:
24 May 2007

Handwritten Signature
Investigator Signature:

Handwritten: 30 May 2007
Date:

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06-Jun-2007

Covance CLS

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LABORATORY REPORT

ACCESSION NO. P060625

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Significant/ Adverse
Event?

Yes

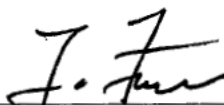
No

sICAM-1

sICAM-1

To follow

R
29 May 2007



Investigator Signature:

30 May 2007
Date:

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QC 20
06-Jun-
2007

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Is this Clinically
Significant/ Adverse
Event?
Yes No

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

J
24 May 2007

Note #1 - No specimen received

J. Farmer
Investigator Signature:

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B17177

(INV)

30 May 2007
Date:

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Covance CLS

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Is this Clinically
Significant/ Adverse
Event?

Yes

No

HAS PATIENT FASTED 8 HOURS?

Fasted?

Yes

[Handwritten Signature]
24 May 2007

[Handwritten Signature: J. Farmer]
Investigator Signature:

30 May 2007
Date:

B17177

QC DD
06 Jun 2007

(INV)

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Yes

No

HEMOGLOBIN A1C

Hgb A1c 5.8

Normals:

4.3-6.1%

Stable Diabetics:

4.2-11.2%

J
24 May 2007

F. Farmer
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Yes

No

OXIDIZED LDL

OxidizeLDL

To follow

h
24 May 2007

F. Farmer

Investigator Signature:

30 May 2007
Date:

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

Testing performed by: Pacific Biometrics

220 West Harrison Street; Seattle, WA 98119

B17177

QC DO
04 Jun 2007
(INV)