

Subject Case Report Forms

1042 (Prod: Covance Clinical Development Services, Daytona Beach, Florida)

Generated On: 20 Jul 2016 11:47:42

All time stamps listed in this document are displayed in GMT

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Form: Subject**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:23**

**Generated On: 20 Jul 2016 11:47:42**

---

|                  |      |
|------------------|------|
| Screening number | 1042 |
|------------------|------|

---

|             |     |
|-------------|-----|
| Site number | DAY |
|-------------|-----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Subject Status**

**Form: Subject Status**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:35**

**Generated On: 20 Jul 2016 11:47:42**

---

Date of 'Screen Failed' Event

---

Date of 'Discontinued From  
Enrollment' Event

---

Randomization Date

16 JAN 2014  
DD/MMM/YYYY

---

Randomization Time

11:27  
hour:min 24-hour clock

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Date of Visit**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:38**

**Generated On: 20 Jul 2016 11:47:42**

---

Date of Visit

08 JAN 2014  
DD/MMM/YYYY

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Additional Informed Consent**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:35**

**Generated On: 20 Jul 2016 11:47:42**

---

Has the subject given written informed consent for  
Bio-banking for Biomarkers of Exposure and Risk  
Markers?

No ☒

---

Consent Date \_\_\_\_\_

---

Has the subject given written informed consent for  
Bio-banking for Transcriptomics (Pharmacogenomics),  
Nasal Epithelial collection and Buccal Collection?

No ☒

---

Consent Date \_\_\_\_\_

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Inclusion Criteria**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:36**

**Generated On: 20 Jul 2016 11:47:42**

---

\*If any has been answered No, subject must not be included in the study.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Inclusion Criteria (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:36**

**Generated On: 20 Jul 2016 11:47:42**

---

|                            |   |
|----------------------------|---|
| Inclusion Criterion Number | 1 |
|----------------------------|---|

---

|                     |   |
|---------------------|---|
| Inclusion Criterion | Subject has signed the ICF<br>and is able to understand<br>the information provided in<br>the Subject Information<br>Sheet and ICF. |
|---------------------|---|

---

|        |     |
|--------|-----|
| Result | Yes |
|--------|-----|

---

\*If any has been answered No, subject must not be included in the study.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Inclusion Criteria (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:36**

**Generated On: 20 Jul 2016 11:47:42**

---

|                            |   |
|----------------------------|---|
| Inclusion Criterion Number | 2 |
|----------------------------|---|

---

|                     |  |                                  |
|---------------------|--|----------------------------------|
| Inclusion Criterion | Subject is at a minimum 22<br>years of age(inclusive). | <input checked="" type="radio"/> |
|---------------------|--|----------------------------------|

---

|        |     |                                  |
|--------|-----|----------------------------------|
| Result | Yes | <input checked="" type="radio"/> |
|--------|-----|----------------------------------|

---

\*If any has been answered No, subject must not be included in the study.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Screening**

**Form: Inclusion Criteria (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:36**

**Generated On: 20 Jul 2016 11:47:42**

---

Inclusion Criterion Number

3

---

Inclusion Criterion

Smoking, apparently healthy subject as judged by the Investigator based on all available assessments from the Screening period/Day of Admission (e.g., safety laboratory, spirometry, vital signs, physical examination, ECG, chest X-ray, and medical history).

---

Result

Yes

---

\*If any has been answered No, subject must not be included in the study.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Screening**

**Form: Inclusion Criteria (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:36**

**Generated On: 20 Jul 2016 11:47:42**

---

|                            |   |
|----------------------------|---|
| Inclusion Criterion Number | 4 |
|----------------------------|---|

---

|                     |   |
|---------------------|---|
| Inclusion Criterion | Subject smokes at least 10 commercially available mCCs per day (no brand restrictions), for the last 4 weeks, based on self-reporting. Furthermore, the subject has been smoking for at least the last 3 consecutive years. The smoking status will be verified based on a urinary cotinine test (cotinine $\geq$ 200 ng/mL). |
|---------------------|---|

---

|        |     |
|--------|-----|
| Result | Yes |
|--------|-----|

---

\*If any has been answered No, subject must not be included in the study.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Inclusion Criteria (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:36**

**Generated On: 20 Jul 2016 11:47:42**

---

|                            |   |
|----------------------------|---|
| Inclusion Criterion Number | 5 |
|----------------------------|---|

---

|                     |  |
|---------------------|--|
| Inclusion Criterion | The subject does not plan to quit smoking within the next 6 months as assessed by the Prochaska 'Stage of Change' questionnaire. |
|---------------------|--|

---

|        |     |
|--------|-----|
| Result | Yes |
|--------|-----|

---

\*If any has been answered No, subject must not be included in the study.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Inclusion Criteria (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:36**

**Generated On: 20 Jul 2016 11:47:42**

---

|                            |   |
|----------------------------|---|
| Inclusion Criterion Number | 6 |
|----------------------------|---|

---

|                     |   |
|---------------------|---|
| Inclusion Criterion | The subject is ready to<br>comply with study protocol<br>(e.g readiness to accept<br>interruptions of smoking<br>for up to 91 days and to<br>use THS 2.2 Menthol ). |
|---------------------|---|

---

|        |     |
|--------|-----|
| Result | Yes |
|--------|-----|

---

\*If any has been answered No, subject must not be included in the study.

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Exclusion Criteria**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:36**

**Generated On: 20 Jul 2016 11:47:42**

---

\*If any has been answered Yes, subject must not be included in the study.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Exclusion Criteria (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:36**

**Generated On: 20 Jul 2016 11:47:42**

---

|                            |   |
|----------------------------|---|
| Exclusion Criterion Number | 1 |
|----------------------------|---|

---

|                     |   |
|---------------------|---|
| Exclusion Criterion | As per Investigator judgment, the subject cannot participate in the study for any reason (e.g., medical, psychiatric and/or social reason). |
|---------------------|---|

---

|        |    |
|--------|----|
| Result | No |
|--------|----|

---

\*If any has been answered Yes, subject must not be included in the study.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Screening**

**Form: Exclusion Criteria (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:36**

**Generated On: 20 Jul 2016 11:47:42**

---

|                            |   |
|----------------------------|---|
| Exclusion Criterion Number | 2 |
|----------------------------|---|

---

|                     |  |
|---------------------|--|
| Exclusion Criterion | A subject who is legally incompetent, physically or mentally incapable of giving consent (e.g., emergency situation, under guardianship, subject in a social or sanitary establishment, prisoners or subjects who are involuntarily incarcerated). |
|---------------------|--|

---

|        |    |
|--------|----|
| Result | No |
|--------|----|

---

\*If any has been answered Yes, subject must not be included in the study.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Screening**

**Form: Exclusion Criteria (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:36**

**Generated On: 20 Jul 2016 11:47:42**

---

Exclusion Criterion Number

3

---

Exclusion Criterion

The subject has clinically relevant diseases which required medications (including but not limited to gastrointestinal, renal, hepatic, neurological, hematological, endocrine, oncological, urological, immunological, pulmonary, and cardiovascular disease or any other medical condition (including safety laboratory as per CTCAE), which in the opinion of the Investigator would jeopardize the safety of the subject.

---

Result

No

---

\*If any has been answered Yes, subject must not be included in the study.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Exclusion Criteria (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:36**

**Generated On: 20 Jul 2016 11:47:42**

---

|                            |   |
|----------------------------|---|
| Exclusion Criterion Number | 4 |
|----------------------------|---|

---

|                     |   |
|---------------------|---|
| Exclusion Criterion | Subject who has forced expiratory volume in 1 second/forced vital capacity (FEV1/FVC) <0.7 and FEV1 <80% predicted value at postbronchodilator spirometry (GOLD, 2013). |
|---------------------|---|

---

|        |                                     |
|--------|-------------------------------------|
| Result | No <input checked="" type="radio"/> |
|--------|-------------------------------------|

---

\*If any has been answered Yes, subject must not be included in the study.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Screening**

**Form: Exclusion Criteria (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:36**

**Generated On: 20 Jul 2016 11:47:42**

---

|                            |   |
|----------------------------|---|
| Exclusion Criterion Number | 5 |
|----------------------------|---|

---

|                     |   |
|---------------------|---|
| Exclusion Criterion | Subject with asthma condition (FEV1/FVC < 0.75 and reversibility in FEV1 > 12% (or > 200 mL) from pre to post-bronchodilator values). |
|---------------------|---|

---

|        |    |
|--------|----|
| Result | No |
|--------|----|

---

\*If any has been answered Yes, subject must not be included in the study.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Exclusion Criteria (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:36**

**Generated On: 20 Jul 2016 11:47:42**

---

|                            |   |
|----------------------------|---|
| Exclusion Criterion Number | 6 |
|----------------------------|---|

---

|                     |   |
|---------------------|---|
| Exclusion Criterion | Subjects with renal insufficiency as defined by serum creatinine levels of >1.3 mg/dL for females and >1.5 mg/dL for males. |
|---------------------|---|

---

|        |    |
|--------|----|
| Result | No |
|--------|----|

---

\*If any has been answered Yes, subject must not be included in the study.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Exclusion Criteria (7)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:36**

**Generated On: 20 Jul 2016 11:47:42**

---

|                            |   |
|----------------------------|---|
| Exclusion Criterion Number | 7 |
|----------------------------|---|

---

|                     |  |
|---------------------|--|
| Exclusion Criterion | The subject has a body mass index (BMI) <18.5 or $\geq 35$ kg/m <sup>2</sup> . |
|---------------------|--|

---

|        |    |
|--------|----|
| Result | No |
|--------|----|

---

\*If any has been answered Yes, subject must not be included in the study.

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Screening**

**Form: Exclusion Criteria (8)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:36**

**Generated On: 20 Jul 2016 11:47:42**

---

|                            |   |
|----------------------------|---|
| Exclusion Criterion Number | 8 |
|----------------------------|---|

---

|                     |   |
|---------------------|---|
| Exclusion Criterion | As per Investigator judgment, the subject has medical conditions which require or will require in the course of the study, a medical intervention (e.g., start of treatment, surgery, hospitalization) which may interfere with the study participation and/or study results. |
|---------------------|---|

---

|        |    |
|--------|----|
| Result | No |
|--------|----|

---

\*If any has been answered Yes, subject must not be included in the study.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Exclusion Criteria (9)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:36**

**Generated On: 20 Jul 2016 11:47:42**

---

|                            |   |
|----------------------------|---|
| Exclusion Criterion Number | 9 |
|----------------------------|---|

---

|                     |  |
|---------------------|--|
| Exclusion Criterion | Any subject with an history of adverse events linked to caffeine or caffeine containing drugs (e.g., Vivarin), such as but not limited to hypersensitivity or allergy. |
|---------------------|--|

---

|        |    |
|--------|----|
| Result | No |
|--------|----|

---

\*If any has been answered Yes, subject must not be included in the study.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Screening**

**Form: Exclusion Criteria (10)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:36**

**Generated On: 20 Jul 2016 11:47:42**

---

|                            |    |
|----------------------------|----|
| Exclusion Criterion Number | 10 |
|----------------------------|----|

---

|                     |   |
|---------------------|---|
| Exclusion Criterion | The subject has used nicotine-containing products other than commercially available mCC (either tobacco-based products or NRT), as well as electronic cigarettes and similar devices, within 4 weeks prior to assessment. |
|---------------------|---|

---

|        |                                     |
|--------|-------------------------------------|
| Result | No <input checked="" type="radio"/> |
|--------|-------------------------------------|

---

\*If any has been answered Yes, subject must not be included in the study.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Exclusion Criteria (11)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:36**

**Generated On: 20 Jul 2016 11:47:42**

---

|                            |    |
|----------------------------|----|
| Exclusion Criterion Number | 12 |
|----------------------------|----|

---

|                     |   |
|---------------------|---|
| Exclusion Criterion | <p>If a subject has received any medication (prescribed or over-the-counter) within 14 days prior to Screening or prior to the Admission Day (Day -2), it will be decided at the discretion of the Investigator if these can potentially interfere with the study objectives or subject's safety.</p> |
|---------------------|---|

---

|        |                                     |
|--------|-------------------------------------|
| Result | No <input checked="" type="radio"/> |
|--------|-------------------------------------|

---

\*If any has been answered Yes, subject must not be included in the study.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Exclusion Criteria (12)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:36**

**Generated On: 20 Jul 2016 11:47:42**

---

|                            |    |
|----------------------------|----|
| Exclusion Criterion Number | 13 |
|----------------------------|----|

---

|                     |   |
|---------------------|---|
| Exclusion Criterion | Concomitant use of<br>nonsteroidal<br>anti-inflammatory drugs<br>(NSAIDs) or acetylsalicylic<br>acid. |
|---------------------|---|

---

|        |                                     |
|--------|-------------------------------------|
| Result | No <input checked="" type="radio"/> |
|--------|-------------------------------------|

---

\*If any has been answered Yes, subject must not be included in the study.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Exclusion Criteria (13)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:36**

**Generated On: 20 Jul 2016 11:47:42**

---

|                            |    |
|----------------------------|----|
| Exclusion Criterion Number | 14 |
|----------------------------|----|

---

|                     |   |
|---------------------|---|
| Exclusion Criterion | The subject has a positive alcohol test and/or the subject has a history of alcohol abuse that could interfere with the subject's participation in the study. |
|---------------------|---|

---

|        |                                     |
|--------|-------------------------------------|
| Result | No <input checked="" type="radio"/> |
|--------|-------------------------------------|

---

\*If any has been answered Yes, subject must not be included in the study.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Exclusion Criteria (14)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:36**

**Generated On: 20 Jul 2016 11:47:42**

---

|                            |    |
|----------------------------|----|
| Exclusion Criterion Number | 15 |
|----------------------------|----|

---

|                     |  |
|---------------------|--|
| Exclusion Criterion | The subject has a positive urine drug test. <input checked="" type="radio"/> |
|---------------------|--|

---

|        |                          |
|--------|--------------------------|
| Result | No <input type="radio"/> |
|--------|--------------------------|

---

\*If any has been answered Yes, subject must not be included in the study.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Exclusion Criteria (15)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:36**

**Generated On: 20 Jul 2016 11:47:42**

---

|                            |    |
|----------------------------|----|
| Exclusion Criterion Number | 16 |
|----------------------------|----|

---

|                     |  |
|---------------------|--|
| Exclusion Criterion | Positive serology test for<br>human immunodeficiency<br>virus (HIV)1/2, hepatitis B<br>or hepatitis C. |
|---------------------|--|

---

|        |    |
|--------|----|
| Result | No |
|--------|----|

---

\*If any has been answered Yes, subject must not be included in the study.

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Exclusion Criteria (16)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:36**

**Generated On: 20 Jul 2016 11:47:42**

---

|                            |    |
|----------------------------|----|
| Exclusion Criterion Number | 17 |
|----------------------------|----|

---

|                     |  |                                  |
|---------------------|--|----------------------------------|
| Exclusion Criterion | Donation or receipt of whole blood or blood products within 3 months prior to Admission. | <input checked="" type="radio"/> |
|---------------------|--|----------------------------------|

---

|        |    |                                  |
|--------|----|----------------------------------|
| Result | No | <input checked="" type="radio"/> |
|--------|----|----------------------------------|

---

\*If any has been answered Yes, subject must not be included in the study.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Exclusion Criteria (17)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:36**

**Generated On: 20 Jul 2016 11:47:42**

---

|                            |    |
|----------------------------|----|
| Exclusion Criterion Number | 18 |
|----------------------------|----|

---

|                     |  |
|---------------------|--|
| Exclusion Criterion | The subject is a current or former employee of the tobacco industry or of their first-degree relatives (parent, sibling, child). |
|---------------------|--|

---

|        |    |
|--------|----|
| Result | No |
|--------|----|

---

\*If any has been answered Yes, subject must not be included in the study.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Exclusion Criteria (18)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:36**

**Generated On: 20 Jul 2016 11:47:42**

---

|                            |    |
|----------------------------|----|
| Exclusion Criterion Number | 19 |
|----------------------------|----|

---

|                     |  |
|---------------------|--|
| Exclusion Criterion | The subject is an employee of the investigational site or any other parties involved in the study or of their first degree relatives (parent, sibling, and child). |
|---------------------|--|

---

|        |    |
|--------|----|
| Result | No |
|--------|----|

---

\*If any has been answered Yes, subject must not be included in the study.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Exclusion Criteria (19)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:36**

**Generated On: 20 Jul 2016 11:47:42**

---

|                            |    |
|----------------------------|----|
| Exclusion Criterion Number | 20 |
|----------------------------|----|

---

|                     |  |
|---------------------|--|
| Exclusion Criterion | The subject has participated in a clinical study within 3 months prior to the Screening Visit. |
|---------------------|--|

---

|        |    |
|--------|----|
| Result | No |
|--------|----|

---

\*If any has been answered Yes, subject must not be included in the study.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Exclusion Criteria (20)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:36**

**Generated On: 20 Jul 2016 11:47:42**

---

|                            |    |
|----------------------------|----|
| Exclusion Criterion Number | 21 |
|----------------------------|----|

---

|                     |  |                       |
|---------------------|--|-----------------------|
| Exclusion Criterion | For women only: Subject is pregnant (does not have negative pregnancy tests at Screening and at Admission) or is breast feeding. | <input type="radio"/> |
|---------------------|--|-----------------------|

---

|        |    |                       |
|--------|----|-----------------------|
| Result | No | <input type="radio"/> |
|--------|----|-----------------------|

---

\*If any has been answered Yes, subject must not be included in the study.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Exclusion Criteria (21)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:36**

**Generated On: 20 Jul 2016 11:47:42**

---

|                            |    |
|----------------------------|----|
| Exclusion Criterion Number | 22 |
|----------------------------|----|

---

|                     |   |
|---------------------|---|
| Exclusion Criterion | For women only : Subject<br>does not agree to use an<br>acceptable method of<br>effective contraception |
|---------------------|---|

---

|        |    |
|--------|----|
| Result | No |
|--------|----|

---

\*If any has been answered Yes, subject must not be included in the study.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Demographics**

**Generated On: 20 Jul 2016 11:47:42**

---

Date of Birth

(b) (6)

---

Sex

Female

---

Race

---

Other, specify

---

Ethnicity

---

Date the Subject signed the Informed Consent

08 JAN 2014  
DD/MMM/YYYY

---

Time the Subject signed the Informed Consent

---

Age(Derived)

48

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Medical History/Concomitant Disease**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:36**

**Generated On: 20 Jul 2016 11:47:42**

---

Date of collection

08 JAN 2014  
DD/MMM/YYYY

---

Has the subject experienced any past and/ or  
concomitant diseases?

Yes ☒



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Medical History/Concomitant Disease (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:36**

**Generated On: 20 Jul 2016 11:47:42**

---

|                    |                            |
|--------------------|----------------------------|
| Date of collection | 08 JAN 2014<br>DD/MMM/YYYY |
|--------------------|----------------------------|

---

|   |                                      |
|---|--------------------------------------|
| Has the subject experienced any past and/ or<br>concomitant diseases? | Yes <input checked="" type="radio"/> |
|---|--------------------------------------|

---

|        |   |
|--------|---|
| Number | 1 |
|--------|---|

---

|                       |            |
|-----------------------|------------|
| Diagnosis Description | PRESBYOPIA |
|-----------------------|------------|

---

|                           |             |
|---------------------------|-------------|
| Onset Date<br>DD/MMM/YYYY | UN UNK 2012 |
|---------------------------|-------------|

---

|                          |  |
|--------------------------|--|
| Stop Date<br>DD/MMM/YYYY |  |
|--------------------------|--|

---

|          |      |
|----------|------|
| Ongoing? | True |
|----------|------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Medical History/Concomitant Disease (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:36**

**Generated On: 20 Jul 2016 11:47:42**

---

|                    |                            |
|--------------------|----------------------------|
| Date of collection | 08 JAN 2014<br>DD/MMM/YYYY |
|--------------------|----------------------------|

---

|   |                                      |
|---|--------------------------------------|
| Has the subject experienced any past and/ or<br>concomitant diseases? | Yes <input checked="" type="radio"/> |
|---|--------------------------------------|

---

|        |   |
|--------|---|
| Number | 2 |
|--------|---|

---

|                       |                |
|-----------------------|----------------|
| Diagnosis Description | TUBAL LIGATION |
|-----------------------|----------------|

---

|                           |             |
|---------------------------|-------------|
| Onset Date<br>DD/MMM/YYYY | 29 DEC 1989 |
|---------------------------|-------------|

---

|                          |             |
|--------------------------|-------------|
| Stop Date<br>DD/MMM/YYYY | 29 DEC 1989 |
|--------------------------|-------------|

---

|          |       |
|----------|-------|
| Ongoing? | False |
|----------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Medical History/Concomitant Disease (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:36**

**Generated On: 20 Jul 2016 11:47:42**

---

|                    |                            |
|--------------------|----------------------------|
| Date of collection | 08 JAN 2014<br>DD/MMM/YYYY |
|--------------------|----------------------------|

---

|   |                                      |
|---|--------------------------------------|
| Has the subject experienced any past and/ or<br>concomitant diseases? | Yes <input checked="" type="radio"/> |
|---|--------------------------------------|

---

|        |   |
|--------|---|
| Number | 3 |
|--------|---|

---

|                       |                   |
|-----------------------|-------------------|
| Diagnosis Description | TENSION HEADACHES |
|-----------------------|-------------------|

---

|                           |             |
|---------------------------|-------------|
| Onset Date<br>DD/MMM/YYYY | 03 JAN 2014 |
|---------------------------|-------------|

---

|                          |  |
|--------------------------|--|
| Stop Date<br>DD/MMM/YYYY |  |
|--------------------------|--|

---

|          |      |
|----------|------|
| Ongoing? | True |
|----------|------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Vital Signs<Screening/<**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:38**

**Generated On: 20 Jul 2016 11:47:42**

---

Were Vitals Signs assessed? Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

Has the subject smoked within 15 minutes prior to assessment No ☒

---

Date of assessment 08 JAN 2014  
DD/MMM/YYYY

---

Time of assessment 11:07  
hour:min 24-hour clock

---

Pulse rate 82  
beats per minute

---

Respiratory rate 18  
breaths per minute

---

Blood Pressure (systolic) 128  
mmHg

---

Blood Pressure (diastolic) 85  
mmHg

---

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Physical Examination**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:37**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed?

Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

Date of assessment

08 JAN 2014  
DD/MMM/YYYY

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Physical Examination (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:37**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed? Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

Date of assessment 08 JAN 2014  
DD/MMM/YYYY

---

System General Appearance ☒

---

Outcome Normal ☒

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done False

---

Not Done; please specify the reason: \_\_\_\_\_

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Physical Examination (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:37**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed?

Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

Date of assessment

08 JAN 2014  
DD/MMM/YYYY

---

System

HEENT ☒  
(head, eyes, ears, nose,  
throat)

---

Outcome

Normal ☒

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done

False

---

Not Done; please specify the reason: \_\_\_\_\_

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Physical Examination (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:37**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed? Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

Date of assessment 08 JAN 2014  
DD/MMM/YYYY

---

System Thyroid Gland ☒

---

Outcome Normal ☒

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done False

---

Not Done; please specify the reason: \_\_\_\_\_



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Physical Examination (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:37**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed? Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

Date of assessment 08 JAN 2014  
DD/MMM/YYYY

---

System Heart ☒

---

Outcome Normal ☒

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done False

---

Not Done; please specify the reason: \_\_\_\_\_

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Physical Examination (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:37**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed? Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

Date of assessment 08 JAN 2014  
DD/MMM/YYYY

---

System Chest ☒

---

Outcome Normal ☒

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done False

---

Not Done; please specify the reason: \_\_\_\_\_

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Physical Examination (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:37**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed?

Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

Date of assessment

08 JAN 2014  
DD/MMM/YYYY

---

System

Lungs ☒

---

Outcome

Normal ☒

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done

False

---

Not Done; please specify the reason: \_\_\_\_\_

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Physical Examination (7)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:37**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed? Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

Date of assessment 08 JAN 2014  
DD/MMM/YYYY

---

System Gastrointestinal ☒

---

Outcome Normal ☒

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done False

---

Not Done; please specify the reason: \_\_\_\_\_

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Physical Examination (8)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:37**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed? Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

Date of assessment 08 JAN 2014  
DD/MMM/YYYY

---

System Cardiovascular System ☒

---

Outcome Normal ☒

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done False

---

Not Done; please specify the reason: \_\_\_\_\_

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Physical Examination (9)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:37**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed? Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

Date of assessment 08 JAN 2014  
DD/MMM/YYYY

---

System Neurologic ☒

---

Outcome Normal ☒

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done False

---

Not Done; please specify the reason: \_\_\_\_\_

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Physical Examination (10)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:37**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed? Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

Date of assessment 08 JAN 2014  
DD/MMM/YYYY

---

System Skin ☒

---

Outcome Normal ☒

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done False

---

Not Done; please specify the reason: \_\_\_\_\_

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Physical Examination (11)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:37**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed? Yes ☐

---

If No, please specify the reason: \_\_\_\_\_

---

Date of assessment 08 JAN 2014  
DD/MMM/YYYY

---

System Back ☐

---

Outcome Normal ☐

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done False

---

Not Done; please specify the reason: \_\_\_\_\_



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Physical Examination (12)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:37**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed? Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

Date of assessment 08 JAN 2014  
DD/MMM/YYYY

---

System Musculoskeletal ☒

---

Outcome Normal ☒

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done False

---

Not Done; please specify the reason: \_\_\_\_\_

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Physical Examination (13)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:37**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed? Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

Date of assessment 08 JAN 2014  
DD/MMM/YYYY

---

System Abdomen ☒

---

Outcome Normal ☒

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done False

---

Not Done; please specify the reason: \_\_\_\_\_

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Physical Examination (14)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:37**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed? Yes ☐

---

If No, please specify the reason: \_\_\_\_\_

---

Date of assessment 08 JAN 2014  
DD/MMM/YYYY

---

System Dentition ☐

---

Outcome Normal ☐

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done False

---

Not Done; please specify the reason: \_\_\_\_\_

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Physical Examination (15)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:37**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed?

Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

Date of assessment

08 JAN 2014  
DD/MMM/YYYY

---

System

Other ☒

---

Other, Specify \_\_\_\_\_

---

Outcome \_\_\_\_\_

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done

True

---

Not Done; please specify the reason: \_\_\_\_\_

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Physical Examination (16)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:37**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed?

Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

Date of assessment

08 JAN 2014  
DD/MMM/YYYY

---

System

Other ☒

---

Other, Specify \_\_\_\_\_

---

Outcome \_\_\_\_\_

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done

True

---

Not Done; please specify the reason: \_\_\_\_\_

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Physical Examination (17)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:37**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed?

Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

Date of assessment

08 JAN 2014  
DD/MMM/YYYY

---

System

Other ☒

---

Other, Specify \_\_\_\_\_

---

Outcome \_\_\_\_\_

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done

True

---

Not Done; please specify the reason: \_\_\_\_\_

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Physical Examination (18)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:37**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed?

Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

Date of assessment

08 JAN 2014  
DD/MMM/YYYY

---

System

Other ☒

---

Other, Specify \_\_\_\_\_

---

Outcome \_\_\_\_\_

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done

True

---

Not Done; please specify the reason: \_\_\_\_\_

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Physical Examination (19)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:37**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed?

Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

Date of assessment

08 JAN 2014  
DD/MMM/YYYY

---

System

Other ☒

---

Other, Specify \_\_\_\_\_

---

Outcome \_\_\_\_\_

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done

True

---

Not Done; please specify the reason: \_\_\_\_\_

NOT EXAMINED



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Advice on the risk of smoking and debriefing**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:38**

**Generated On: 20 Jul 2016 11:47:42**

---

Has the subject received advices on the risks of  
smoking?

Yes ☒

---

Has a debriefing been performed about THS 2.2?

Yes ☒

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Identification of Current Cigarette Brand**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:38**

**Generated On: 20 Jul 2016 11:47:42**

---

Date

08 JAN 2014  
DD/MMM/YYYY

---

Brand name

305 MENTHOL 100'S

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: THS 2.2 menthol product demonstration**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:38**

**Generated On: 20 Jul 2016 11:47:42**

---

Has the subject seen a THS 2.2 menthol product  
demonstration?

Yes ☒

---

If the subject did not see the demonstration please  
explain

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Smoking History**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:38**

**Generated On: 20 Jul 2016 11:47:42**

---

Date of Assessment

08 JAN 2014  
DD/MMM/YYYY

---

1. Does the subject plan to quit smoking during the next  
6 months?

No ☐

---

2. Did the subject smoke for at least 3 consecutive  
years?

Yes ☐

---

3. How many menthol cigarettes per day has the subject  
smoked on average during the last 4 weeks?

10 to 19 ☐

---

4. Did the subject smoke menthol cigarettes in the last 4  
weeks?

Yes ☐

---

5. The subject has used nicotine-containing products  
other than commercially available mCC (either  
tobacco-based products or nicotine-replacement therapy  
[NRT]), electronic cigarettes and similar devices, within 4  
weeks prior to assessment.

No ☐

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Weight and Height**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:39**

**Generated On: 20 Jul 2016 11:47:42**

---

Measurement(s) assessed?

Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

Date of assessment

08 JAN 2014  
DD/MMM/YYYY

---

Weight

68.9  
kg

---

Height

166.5  
cm

---

BMI (Derived)

24.9  
kg/m2

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: ECG (12-Lead Standard)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:35**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the ECG performed? Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

---

Date of assessment: 08 JAN 2014  
DD/MMM/YYYY

---

---

Position Supine ☒

---

---

Heart Rate 85  
beats per minute

---

---

QRS Interval 82  
msec

---

---

QT Interval 365  
msec

---

---

QTcB Interval 435  
msec

---

---

QTcF Interval 410  
msec

---

---

PR Interval 137  
msec

---

---

Interpretation Normal ☒

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: ECG (12-Lead Standard)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:35**

**Generated On: 20 Jul 2016 11:47:42**

---

If Abnormal, Clinical Significance \_\_\_\_\_

---

If Not Clinically significant or clinically Significant, Please  
specify the finding(s) \_\_\_\_\_

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Spirometry (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:38**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the spirometry performed? Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

Category Without short-acting ☒  
bronchodilator

---

Position SITTING

---

Has the subject smoked within 1 hour prior to assessment? No ☒

---

Date of assessment DD/MMM/YYYY 08 JAN 2014

---

Time of assessment 11:50

---

Predicted FVC value 3.14  
L

---

Best measured FVC value 3.32  
L

---

Percent of predicted FVC value 106  
%

---

Best measured FEV1 value 2.37  
L



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Spirometry (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:38**

**Generated On: 20 Jul 2016 11:47:42**

---

|                      |           |
|----------------------|-----------|
| Predicted FEV1 value | 2.53<br>L |
|----------------------|-----------|

---

|                                 |         |
|---------------------------------|---------|
| Percent of predicted FEV1 value | 94<br>% |
|---------------------------------|---------|

---

|                                   |      |
|-----------------------------------|------|
| Calculated ratio between FEV1/FVC | 0.71 |
|-----------------------------------|------|

---

|                 |             |
|-----------------|-------------|
| MEF 25/75 value | 1.40<br>L/s |
|-----------------|-------------|

---

|                |   |
|----------------|---|
| Interpretation | Normal <input checked="" type="radio"/> |
|----------------|---|

---

|                                    |       |
|------------------------------------|-------|
| If Abnormal, Clinical Significance | <hr/> |
|------------------------------------|-------|

---

|   |       |
|---|-------|
| If Not Clinically Significant or Clinically Significant, Please<br>specify the finding(s) | <hr/> |
|---|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Spirometry (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:38**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the spirometry performed? Yes ☐

---

If No, please specify the reason: \_\_\_\_\_

---

Category With short-acting ☐  
bronchodilator

---

Position SITTING

---

Has the subject smoked within 1 hour prior to assessment? No ☐

---

Date of assessment 08 JAN 2014  
DD/MMM/YYYY

---

Time of assessment 12:16

---

Name of bronchodilator ALBUTEROL SULFATE

---

Dose 180MCG

---

Predicted FVC value 3.14  
L

---

Best measured FVC value 2.80  
L

---

Percent of predicted FVC value 89  
%

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Spirometry (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:38**

**Generated On: 20 Jul 2016 11:47:42**

|   |   |
|---|---|
| Best measured FEV1 value  | 2.40<br>L                               |
| Predicted FEV1 value  | 2.53<br>L                               |
| Percent of predicted FEV1 value   | 95<br>%                                 |
| Calculated ratio between FEV1/FVC   | 0.86                                    |
| MEF 25/75 value   | 3.04<br>L/s                             |
| Interpretation  | Normal <input checked="" type="radio"/> |
| If Abnormal, Clinical Significance  |   |
| If Not Clinically Significant or Clinically Significant, Please<br>specify the finding(s) |   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Chest X-Ray**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:39**

**Generated On: 20 Jul 2016 11:47:42**

---

Was a chest X-Ray with anterior-posterior and left lateral  
views performed?

Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

Date of assessment

13 JAN 2014  
DD/MMM/YYYY

---

System

Chest ☒

---

Interpretation

Normal ☒

---

Clinically significant \_\_\_\_\_

---

Abnormal, please specify: \_\_\_\_\_

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Haematology**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:36**

**Generated On: 20 Jul 2016 11:47:42**

---

Were samples collected?

Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

Was the subject fasting for at least 10 hours at time of  
sample collection?

Yes ☒

---

Please document clinically relevant abnormalities in the AE form

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Clinical Chemistry**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:36**

**Generated On: 20 Jul 2016 11:47:42**

---

Were samples collected?

Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

Was the subject fasting for at least 10 hours at time of  
sample collection?

Yes ☒

---

Please document clinically relevant abnormalities in the AE form

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Urine analysis**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:36**

**Generated On: 20 Jul 2016 11:47:42**

---

Were samples collected?

Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Serology for HIV and Hepatitis B and C**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:36**

**Generated On: 20 Jul 2016 11:47:42**

---

Category

Serology ☒

---

Not Done

False

---

If Not Done, please specify the reason:



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Screening**

**Form: Urine Drug Screen**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:36**

**Generated On: 20 Jul 2016 11:47:42**

---

|           |       |
|-----------|-------|
| Not Done? | False |
|-----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                           |                            |
|---------------------------|----------------------------|
| Date of sample collection | 08 JAN 2014<br>DD/MMM/YYYY |
|---------------------------|----------------------------|

---

|                           |                                 |
|---------------------------|---------------------------------|
| Time of sample collection | 10:58<br>hour:min 24-hour clock |
|---------------------------|---------------------------------|

---

| Drug type       | Result   |
|-----------------|----------|
| Amphetamines    | Negative |
| Barbiturates    | Negative |
| Benzodiazepines | Negative |

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Screening**

**Form: Urine Drug Screen (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:36**

**Generated On: 20 Jul 2016 11:47:42**

---

| Drug type    | Result   |
|--------------|----------|
| Cannabinoids | Negative |
| Cocaine      | Negative |
| Opiates      | Negative |

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Alcohol Test**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:36**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the alcohol test performed? Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

Method used Breath test ☒

---

Date of assessment 08 JAN 2014  
DD/MMM/YYYY

---

Time of assessment 11:16  
hour:min 24-hour clock

---

Result Negative ☒

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Urine Pregnancy Test**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |  |
|----------|--|
| Category | Pregnancy Testing <input checked="" type="radio"/> |
|----------|--|

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

|                             |       |
|-----------------------------|-------|
| If Not Done, specify reason | <hr/> |
|-----------------------------|-------|

---

|              |                            |
|--------------|----------------------------|
| Date of Test | 08 JAN 2014<br>DD/MMM/YYYY |
|--------------|----------------------------|

---

|              |                                 |
|--------------|---------------------------------|
| Time of Test | 11:24<br>hour:min 24-hour clock |
|--------------|---------------------------------|

---

|                |   |
|----------------|---|
| Specify result | Negative <input checked="" type="radio"/> |
|----------------|---|

---

|  |       |
|--|-------|
| If unclear, please confirm with FSH test | <hr/> |
|--|-------|

---

|                            |       |
|----------------------------|-------|
| Specify result of FSH test | <hr/> |
|----------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Urine Cotinine Test**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:36**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |   |
|----------|---|
| Category | Cotinine Screening <input checked="" type="radio"/> |
|----------|---|

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                           |                            |
|---------------------------|----------------------------|
| Date of Sample Collection | 08 JAN 2014<br>DD/MMM/YYYY |
|---------------------------|----------------------------|

---

|                           |                                 |
|---------------------------|---------------------------------|
| Time of Sample Collection | 10:58<br>hour:min 24-hour clock |
|---------------------------|---------------------------------|

---

|        |   |
|--------|---|
| Result | Positive >=200 ng/ml <input checked="" type="radio"/> |
|--------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp CHEMISTRY(08 JAN 2014)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:40**

**Generated On: 20 Jul 2016 11:47:42**

---

Experiment Type

CHEMISTRY

---

Date of Sample Collection  
YYYY/MM/DD

08 JAN 2014

---

Please document clinically relevant abnormalities in the AE form

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp CHEMISTRY(08 JAN 2014)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:40**

**Generated On: 20 Jul 2016 11:47:42**

|   |   |
|---|---|
| Experiment Type                         | CHEMISTRY                               |
| Date of Sample Collection<br>YYYY/MM/DD | 08 JAN 2014                             |
| Subject Number                          |   |
| Date of Birth                           | (b) (6)                                 |
| Gender                                  | Female <input checked="" type="radio"/> |
| Time of Sample Collection               | 11:42                                   |
| Analyte Name                            | GLUCOSE, SERUM                          |
| Code                                    | 001032                                  |
| Result                                  | 90                                      |
| Unit                                    | MG/DL                                   |
| Lower limit                             | 65                                      |
| Upper limit                             | 99                                      |
| Flag                                    |   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp CHEMISTRY(08 JAN 2014)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:40**

**Generated On: 20 Jul 2016 11:47:42**

---

Clinically Significant? \_\_\_\_\_

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

00857100100

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:40**

**Generated On: 20 Jul 2016 11:47:42**

---

|                 |           |
|-----------------|-----------|
| Experiment Type | CHEMISTRY |
|-----------------|-----------|

---

|   |             |
|---|-------------|
| Date of Sample Collection<br>YYYY/MM/DD | 08 JAN 2014 |
|---|-------------|

---

|                |  |
|----------------|--|
| Subject Number |  |
|----------------|--|

---

|               |         |
|---------------|---------|
| Date of Birth | (b) (6) |
|---------------|---------|

---

|        |   |
|--------|---|
| Gender | Female <input checked="" type="radio"/> |
|--------|---|

---

|                           |       |
|---------------------------|-------|
| Time of Sample Collection | 11:42 |
|---------------------------|-------|

---

|              |     |
|--------------|-----|
| Analyte Name | BUN |
|--------------|-----|

---

|      |        |
|------|--------|
| Code | 001040 |
|------|--------|

---

|        |   |
|--------|---|
| Result | 8 |
|--------|---|

---

|      |       |
|------|-------|
| Unit | MG/DL |
|------|-------|

---

|             |   |
|-------------|---|
| Lower limit | 6 |
|-------------|---|

---

|             |    |
|-------------|----|
| Upper limit | 24 |
|-------------|----|

---

|      |  |
|------|--|
| Flag |  |
|------|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:40**

**Generated On: 20 Jul 2016 11:47:42**

---

Clinically Significant? \_\_\_\_\_

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

00857100100

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:40**

**Generated On: 20 Jul 2016 11:47:42**

|   |   |
|---|---|
| Experiment Type                         | CHEMISTRY                               |
| Date of Sample Collection<br>YYYY/MM/DD | 08 JAN 2014                             |
| Subject Number                          |   |
| Date of Birth                           | (b) (6)                                 |
| Gender                                  | Female <input checked="" type="radio"/> |
| Time of Sample Collection               | 11:42                                   |
| Analyte Name                            | CHOLESTEROL, TOTAL                      |
| Code                                    | 001065                                  |
| Result                                  | 167                                     |
| Unit                                    | MG/DL                                   |
| Lower limit                             | 100                                     |
| Upper limit                             | 199                                     |
| Flag                                    |   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:40**

**Generated On: 20 Jul 2016 11:47:42**

---

Clinically Significant? \_\_\_\_\_

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

00857100100

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:40**

**Generated On: 20 Jul 2016 11:47:42**

---

Experiment Type

CHEMISTRY

---

Date of Sample Collection  
YYYY/MM/DD

08 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

11:42

---

Analyte Name

PROTEIN, TOTAL, SERUM

---

Code

001073

---

Result

6.8

---

Unit

G/DL

---

Lower limit

6.0

---

Upper limit

8.5

---

Flag

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:40**

**Generated On: 20 Jul 2016 11:47:42**

---

Clinically Significant? \_\_\_\_\_

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

00857100100

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:40**

**Generated On: 20 Jul 2016 11:47:42**

---

Experiment Type

CHEMISTRY

---

Date of Sample Collection  
YYYY/MM/DD

08 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

11:42

---

Analyte Name

ALBUMIN, SERUM

---

Code

001081

---

Result

4.0

---

Unit

G/DL

---

Lower limit

3.5

---

Upper limit

5.5

---

Flag

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:40**

**Generated On: 20 Jul 2016 11:47:42**

---

Clinically Significant? \_\_\_\_\_

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

00857100100

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:40**

**Generated On: 20 Jul 2016 11:47:42**

|   |   |
|---|---|
| Experiment Type                         | CHEMISTRY                               |
| Date of Sample Collection<br>YYYY/MM/DD | 08 JAN 2014                             |
| Subject Number                          |   |
| Date of Birth                           | (b) (6)                                 |
| Gender                                  | Female <input checked="" type="radio"/> |
| Time of Sample Collection               | 11:42                                   |
| Analyte Name                            | BILIRUBIN, TOTAL                        |
| Code                                    | 001099                                  |
| Result                                  | 0.2                                     |
| Unit                                    | MG/DL                                   |
| Lower limit                             | 0.0                                     |
| Upper limit                             | 1.2                                     |
| Flag                                    |   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:40**

**Generated On: 20 Jul 2016 11:47:42**

---

Clinically Significant? \_\_\_\_\_

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

00857100100

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (7)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:40**

**Generated On: 20 Jul 2016 11:47:42**

---

|                 |           |
|-----------------|-----------|
| Experiment Type | CHEMISTRY |
|-----------------|-----------|

---

|   |             |
|---|-------------|
| Date of Sample Collection<br>YYYY/MM/DD | 08 JAN 2014 |
|---|-------------|

---

|                |  |
|----------------|--|
| Subject Number |  |
|----------------|--|

---

|               |         |
|---------------|---------|
| Date of Birth | (b) (6) |
|---------------|---------|

---

|        |   |
|--------|---|
| Gender | Female <input checked="" type="radio"/> |
|--------|---|

---

|                           |       |
|---------------------------|-------|
| Time of Sample Collection | 11:42 |
|---------------------------|-------|

---

|              |                         |
|--------------|-------------------------|
| Analyte Name | ALKALINE PHOSPHATASE, S |
|--------------|-------------------------|

---

|      |        |
|------|--------|
| Code | 001107 |
|------|--------|

---

|        |    |
|--------|----|
| Result | 53 |
|--------|----|

---

|      |      |
|------|------|
| Unit | IU/L |
|------|------|

---

|             |    |
|-------------|----|
| Lower limit | 39 |
|-------------|----|

---

|             |     |
|-------------|-----|
| Upper limit | 117 |
|-------------|-----|

---

|      |  |
|------|--|
| Flag |  |
|------|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (7)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:40**

**Generated On: 20 Jul 2016 11:47:42**

---

Clinically Significant? \_\_\_\_\_

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

00857100100

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (8)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:40**

**Generated On: 20 Jul 2016 11:47:42**

---

|                 |           |
|-----------------|-----------|
| Experiment Type | CHEMISTRY |
|-----------------|-----------|

---

|   |             |
|---|-------------|
| Date of Sample Collection<br>YYYY/MM/DD | 08 JAN 2014 |
|---|-------------|

---

|                |  |
|----------------|--|
| Subject Number |  |
|----------------|--|

---

|               |         |
|---------------|---------|
| Date of Birth | (b) (6) |
|---------------|---------|

---

|        |   |
|--------|---|
| Gender | Female <input checked="" type="radio"/> |
|--------|---|

---

|                           |       |
|---------------------------|-------|
| Time of Sample Collection | 11:42 |
|---------------------------|-------|

---

|              |     |
|--------------|-----|
| Analyte Name | LDH |
|--------------|-----|

---

|      |        |
|------|--------|
| Code | 001115 |
|------|--------|

---

|        |     |
|--------|-----|
| Result | 159 |
|--------|-----|

---

|      |      |
|------|------|
| Unit | IU/L |
|------|------|

---

|             |   |
|-------------|---|
| Lower limit | 0 |
|-------------|---|

---

|             |     |
|-------------|-----|
| Upper limit | 214 |
|-------------|-----|

---

|      |  |
|------|--|
| Flag |  |
|------|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (8)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:40**

**Generated On: 20 Jul 2016 11:47:42**

---

Clinically Significant? \_\_\_\_\_

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

00857100100

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (9)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:40**

**Generated On: 20 Jul 2016 11:47:42**

---

Experiment Type

CHEMISTRY

---

Date of Sample Collection  
YYYY/MM/DD

08 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

11:42

---

Analyte Name

AST (SGOT)

---

Code

001123

---

Result

17

---

Unit

IU/L

---

Lower limit

0

---

Upper limit

40

---

Flag

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (9)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:40**

**Generated On: 20 Jul 2016 11:47:42**

---

Clinically Significant? \_\_\_\_\_

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

00857100100

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (10)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:40**

**Generated On: 20 Jul 2016 11:47:42**

|   |   |
|---|---|
| Experiment Type                         | CHEMISTRY                               |
| Date of Sample Collection<br>YYYY/MM/DD | 08 JAN 2014                             |
| Subject Number                          |   |
| Date of Birth                           | (b) (6)                                 |
| Gender                                  | Female <input checked="" type="radio"/> |
| Time of Sample Collection               | 11:42                                   |
| Analyte Name                            | TRIGLYCERIDES                           |
| Code                                    | 001172                                  |
| Result                                  | 58                                      |
| Unit                                    | MG/DL                                   |
| Lower limit                             | 0                                       |
| Upper limit                             | 149                                     |
| Flag                                    |   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (10)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:40**

**Generated On: 20 Jul 2016 11:47:42**

---

Clinically Significant? \_\_\_\_\_

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

00857100100

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (11)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:40**

**Generated On: 20 Jul 2016 11:47:42**

|   |   |
|---|---|
| Experiment Type                         | CHEMISTRY                               |
| Date of Sample Collection<br>YYYY/MM/DD | 08 JAN 2014                             |
| Subject Number                          |   |
| Date of Birth                           | (b) (6)                                 |
| Gender                                  | Female <input checked="" type="radio"/> |
| Time of Sample Collection               | 11:42                                   |
| Analyte Name                            | POTASSIUM, SERUM                        |
| Code                                    | 001180                                  |
| Result                                  | 5.2                                     |
| Unit                                    | MMOL/L                                  |
| Lower limit                             | 3.5                                     |
| Upper limit                             | 5.2                                     |
| Flag                                    |   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (11)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:40**

**Generated On: 20 Jul 2016 11:47:42**

---

Clinically Significant? \_\_\_\_\_

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

00857100100

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (12)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:40**

**Generated On: 20 Jul 2016 11:47:42**

|   |   |
|---|---|
| Experiment Type                         | CHEMISTRY                               |
| Date of Sample Collection<br>YYYY/MM/DD | 08 JAN 2014                             |
| Subject Number                          |   |
| Date of Birth                           | (b) (6)                                 |
| Gender                                  | Female <input checked="" type="radio"/> |
| Time of Sample Collection               | 11:42                                   |
| Analyte Name                            | SODIUM, SERUM                           |
| Code                                    | 001198                                  |
| Result                                  | 141                                     |
| Unit                                    | MMOL/L                                  |
| Lower limit                             | 134                                     |
| Upper limit                             | 144                                     |
| Flag                                    |   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (12)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:40**

**Generated On: 20 Jul 2016 11:47:42**

---

Clinically Significant? \_\_\_\_\_

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

00857100100

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (13)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:40**

**Generated On: 20 Jul 2016 11:47:42**

|   |   |
|---|---|
| Experiment Type                         | CHEMISTRY                               |
| Date of Sample Collection<br>YYYY/MM/DD | 08 JAN 2014                             |
| Subject Number                          |   |
| Date of Birth                           | (b) (6)                                 |
| Gender                                  | Female <input checked="" type="radio"/> |
| Time of Sample Collection               | 11:42                                   |
| Analyte Name                            | BILIRUBIN, DIRECT                       |
| Code                                    | 001222                                  |
| Result                                  | 0.10                                    |
| Unit                                    | MG/DL                                   |
| Lower limit                             | 0.00                                    |
| Upper limit                             | 0.40                                    |
| Flag                                    |   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (13)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:40**

**Generated On: 20 Jul 2016 11:47:42**

---

Clinically Significant? \_\_\_\_\_

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

00857100100

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (14)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:40**

**Generated On: 20 Jul 2016 11:47:42**

|   |   |
|---|---|
| Experiment Type                         | CHEMISTRY                               |
| Date of Sample Collection<br>YYYY/MM/DD | 08 JAN 2014                             |
| Subject Number                          |   |
| Date of Birth                           | (b) (6)                                 |
| Gender                                  | Female <input checked="" type="radio"/> |
| Time of Sample Collection               | 11:42                                   |
| Analyte Name                            | CREATININE, SERUM                       |
| Code                                    | 001370                                  |
| Result                                  | 0.67                                    |
| Unit                                    | MG/DL                                   |
| Lower limit                             | 0.57                                    |
| Upper limit                             | 1.00                                    |
| Flag                                    |   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (14)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:40**

**Generated On: 20 Jul 2016 11:47:42**

---

Clinically Significant? \_\_\_\_\_

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

00857100100

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (15)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:40**

**Generated On: 20 Jul 2016 11:47:42**

|   |   |
|---|---|
| Experiment Type                         | CHEMISTRY                               |
| Date of Sample Collection<br>YYYY/MM/DD | 08 JAN 2014                             |
| Subject Number                          |   |
| Date of Birth                           | (b) (6)                                 |
| Gender                                  | Female <input checked="" type="radio"/> |
| Time of Sample Collection               | 11:42                                   |
| Analyte Name                            | ALT (SGPT)                              |
| Code                                    | 001545                                  |
| Result                                  | 14                                      |
| Unit                                    | IU/L                                    |
| Lower limit                             | 0                                       |
| Upper limit                             | 32                                      |
| Flag                                    |   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (15)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:40**

**Generated On: 20 Jul 2016 11:47:42**

---

Clinically Significant? \_\_\_\_\_

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

00857100100

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (16)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:40**

**Generated On: 20 Jul 2016 11:47:42**

---

Experiment Type

CHEMISTRY

---

Date of Sample Collection  
YYYY/MM/DD

08 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

11:42

---

Analyte Name

GGT

---

Code

001958

---

Result

20

---

Unit

IU/L

---

Lower limit

0

---

Upper limit

60

---

Flag

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (16)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:40**

**Generated On: 20 Jul 2016 11:47:42**

---

Clinically Significant? \_\_\_\_\_

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

00857100100

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (17)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:40**

**Generated On: 20 Jul 2016 11:47:42**

|   |   |
|---|---|
| Experiment Type                         | CHEMISTRY                               |
| Date of Sample Collection<br>YYYY/MM/DD | 08 JAN 2014                             |
| Subject Number                          |   |
| Date of Birth                           | (b) (6)                                 |
| Gender                                  | Female <input checked="" type="radio"/> |
| Time of Sample Collection               | 11:42                                   |
| Analyte Name                            | HEP C VIRUS AB                          |
| Code                                    | 140683                                  |
| Result                                  | <0.1                                    |
| Unit                                    | S/CO RATIO                              |
| Lower limit                             | 0.0                                     |
| Upper limit                             | 0.9                                     |
| Flag                                    |   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (17)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:40**

**Generated On: 20 Jul 2016 11:47:42**

---

Clinically Significant? \_\_\_\_\_

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

00857100100

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp SEROLOGY(08 JAN 2014)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:43**

**Generated On: 20 Jul 2016 11:47:42**

---

Experiment Type

SEROLOGY

---

Date of Sample Collection  
YYYY/MM/DD

08 JAN 2014

---

Please document clinically relevant abnormalities in the AE form

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp SEROLOGY(08 JAN 2014)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:43**

**Generated On: 20 Jul 2016 11:47:42**

---

|                 |          |
|-----------------|----------|
| Experiment Type | SEROLOGY |
|-----------------|----------|

---

|   |             |
|---|-------------|
| Date of Sample Collection<br>YYYY/MM/DD | 08 JAN 2014 |
|---|-------------|

---

|                |  |
|----------------|--|
| Subject Number |  |
|----------------|--|

---

|               |         |
|---------------|---------|
| Date of Birth | (b) (6) |
|---------------|---------|

---

|        |   |
|--------|---|
| Gender | Female <input checked="" type="radio"/> |
|--------|---|

---

|                           |       |
|---------------------------|-------|
| Time of Sample Collection | 11:42 |
|---------------------------|-------|

---

|              |                     |
|--------------|---------------------|
| Analyte Name | HIV 1/O/2 ABS, QUAL |
|--------------|---------------------|

---

|      |        |
|------|--------|
| Code | 001725 |
|------|--------|

---

|        |              |
|--------|--------------|
| Result | NON REACTIVE |
|--------|--------------|

---

|      |  |
|------|--|
| Unit |  |
|------|--|

---

|             |              |
|-------------|--------------|
| Lower limit | NON REACTIVE |
|-------------|--------------|

---

|             |  |
|-------------|--|
| Upper limit |  |
|-------------|--|

---

|      |  |
|------|--|
| Flag |  |
|------|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp SEROLOGY(08 JAN 2014)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:43**

**Generated On: 20 Jul 2016 11:47:42**

---

Clinically Significant? \_\_\_\_\_

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

00857100100

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:43**

**Generated On: 20 Jul 2016 11:47:42**

---

Experiment Type

SEROLOGY

---

Date of Sample Collection  
YYYY/MM/DD

08 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

11:42

---

Analyte Name

HBSAG SCREEN

---

Code

006510

---

Result

NEGATIVE

---

Unit

---

Lower limit

NEGATIVE

---

Upper limit

---

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:43**

**Generated On: 20 Jul 2016 11:47:42**

---

Clinically Significant? \_\_\_\_\_

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

00857100100

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:43**

**Generated On: 20 Jul 2016 11:47:42**

---

Experiment Type

SEROLOGY

---

Date of Sample Collection  
YYYY/MM/DD

08 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

11:42

---

Analyte Name

HIV 1/O/2 ABS-INDEX VALUE

---

Code

150010

---

Result

<1.00

---

Unit

---

Lower limit

<1.00

---

Upper limit

---

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:43**

**Generated On: 20 Jul 2016 11:47:42**

---

Clinically Significant? \_\_\_\_\_

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

00857100100

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp HEMATOLOGY(08 JAN 2014)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:44**

**Generated On: 20 Jul 2016 11:47:42**

---

Experiment Type

HEMATOLOGY

---

Date of Sample Collection  
YYYY/MM/DD

08 JAN 2014

---

Please document clinically relevant abnormalities in the AE form

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp HEMATOLOGY(08 JAN 2014)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:44**

**Generated On: 20 Jul 2016 11:47:42**

|   |   |
|---|---|
| Experiment Type                         | HEMATOLOGY                              |
| Date of Sample Collection<br>YYYY/MM/DD | 08 JAN 2014                             |
| Subject Number                          |   |
| Date of Birth                           | (b) (6)                                 |
| Gender                                  | Female <input checked="" type="radio"/> |
| Time of Sample Collection               | 11:42                                   |
| Analyte Name                            | WBC                                     |
| Code                                    | 005025                                  |
| Result                                  | 6.1                                     |
| Unit                                    | X10E3/UL                                |
| Lower limit                             | 3.4                                     |
| Upper limit                             | 10.8                                    |
| Flag                                    |   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp HEMATOLOGY(08 JAN 2014)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:44**

**Generated On: 20 Jul 2016 11:47:42**

---

Clinically Significant? \_\_\_\_\_

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

00857100100

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:44**

**Generated On: 20 Jul 2016 11:47:42**

---

Experiment Type

HEMATOLOGY

---

Date of Sample Collection  
YYYY/MM/DD

08 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

11:42

---

Analyte Name

RBC

---

Code

005033

---

Result

3.96

---

Unit

X10E6/UL

---

Lower limit

3.77

---

Upper limit

5.28

---

Flag

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:44**

**Generated On: 20 Jul 2016 11:47:42**

---

Clinically Significant? \_\_\_\_\_

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

00857100100

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:44**

**Generated On: 20 Jul 2016 11:47:42**

---

|                 |            |
|-----------------|------------|
| Experiment Type | HEMATOLOGY |
|-----------------|------------|

---

|   |             |
|---|-------------|
| Date of Sample Collection<br>YYYY/MM/DD | 08 JAN 2014 |
|---|-------------|

---

|                |  |
|----------------|--|
| Subject Number |  |
|----------------|--|

---

|               |         |
|---------------|---------|
| Date of Birth | (b) (6) |
|---------------|---------|

---

|        |   |
|--------|---|
| Gender | Female <input checked="" type="radio"/> |
|--------|---|

---

|                           |       |
|---------------------------|-------|
| Time of Sample Collection | 11:42 |
|---------------------------|-------|

---

|              |            |
|--------------|------------|
| Analyte Name | HEMOGLOBIN |
|--------------|------------|

---

|      |        |
|------|--------|
| Code | 005041 |
|------|--------|

---

|        |      |
|--------|------|
| Result | 11.7 |
|--------|------|

---

|      |      |
|------|------|
| Unit | G/DL |
|------|------|

---

|             |      |
|-------------|------|
| Lower limit | 11.1 |
|-------------|------|

---

|             |      |
|-------------|------|
| Upper limit | 15.9 |
|-------------|------|

---

|      |  |
|------|--|
| Flag |  |
|------|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:44**

**Generated On: 20 Jul 2016 11:47:42**

---

Clinically Significant? \_\_\_\_\_

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

00857100100

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:44**

**Generated On: 20 Jul 2016 11:47:42**

|   |   |
|---|---|
| Experiment Type                         | HEMATOLOGY                              |
| Date of Sample Collection<br>YYYY/MM/DD | 08 JAN 2014                             |
| Subject Number                          |   |
| Date of Birth                           | (b) (6)                                 |
| Gender                                  | Female <input checked="" type="radio"/> |
| Time of Sample Collection               | 11:42                                   |
| Analyte Name                            | HEMATOCRIT                              |
| Code                                    | 005058                                  |
| Result                                  | 36.4                                    |
| Unit                                    | %                                       |
| Lower limit                             | 34.0                                    |
| Upper limit                             | 46.6                                    |
| Flag                                    |   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:44**

**Generated On: 20 Jul 2016 11:47:42**

---

Clinically Significant? \_\_\_\_\_

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

00857100100

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:44**

**Generated On: 20 Jul 2016 11:47:42**

|   |   |
|---|---|
| Experiment Type                         | HEMATOLOGY                              |
| Date of Sample Collection<br>YYYY/MM/DD | 08 JAN 2014                             |
| Subject Number                          |   |
| Date of Birth                           | (b) (6)                                 |
| Gender                                  | Female <input checked="" type="radio"/> |
| Time of Sample Collection               | 11:42                                   |
| Analyte Name                            | MCV                                     |
| Code                                    | 015065                                  |
| Result                                  | 92                                      |
| Unit                                    | FL                                      |
| Lower limit                             | 79                                      |
| Upper limit                             | 97                                      |
| Flag                                    |   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:44**

**Generated On: 20 Jul 2016 11:47:42**

---

Clinically Significant? \_\_\_\_\_

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

00857100100

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:44**

**Generated On: 20 Jul 2016 11:47:42**

|   |   |
|---|---|
| Experiment Type                         | HEMATOLOGY                              |
| Date of Sample Collection<br>YYYY/MM/DD | 08 JAN 2014                             |
| Subject Number                          |   |
| Date of Birth                           | (b) (6)                                 |
| Gender                                  | Female <input checked="" type="radio"/> |
| Time of Sample Collection               | 11:42                                   |
| Analyte Name                            | MCH                                     |
| Code                                    | 015073                                  |
| Result                                  | 29.5                                    |
| Unit                                    | PG                                      |
| Lower limit                             | 26.6                                    |
| Upper limit                             | 33.0                                    |
| Flag                                    |   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:44**

**Generated On: 20 Jul 2016 11:47:42**

---

Clinically Significant? \_\_\_\_\_

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

00857100100

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (7)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:44**

**Generated On: 20 Jul 2016 11:47:42**

---

Experiment Type

HEMATOLOGY

---

Date of Sample Collection  
YYYY/MM/DD

08 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

11:42

---

Analyte Name

MCHC

---

Code

015081

---

Result

32.1

---

Unit

G/DL

---

Lower limit

31.5

---

Upper limit

35.7

---

Flag

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (7)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:44**

**Generated On: 20 Jul 2016 11:47:42**

---

Clinically Significant? \_\_\_\_\_

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

00857100100

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (8)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:44**

**Generated On: 20 Jul 2016 11:47:42**

|   |   |
|---|---|
| Experiment Type                         | HEMATOLOGY                              |
| Date of Sample Collection<br>YYYY/MM/DD | 08 JAN 2014                             |
| Subject Number                          |   |
| Date of Birth                           | (b) (6)                                 |
| Gender                                  | Female <input checked="" type="radio"/> |
| Time of Sample Collection               | 11:42                                   |
| Analyte Name                            | NEUTROPHILS                             |
| Code                                    | 015107                                  |
| Result                                  | 55                                      |
| Unit                                    | %                                       |
| Lower limit                             | 40                                      |
| Upper limit                             | 74                                      |
| Flag                                    |   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (8)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:44**

**Generated On: 20 Jul 2016 11:47:42**

---

Clinically Significant? \_\_\_\_\_

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

00857100100

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (9)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:44**

**Generated On: 20 Jul 2016 11:47:42**

|   |   |
|---|---|
| Experiment Type                         | HEMATOLOGY                              |
| Date of Sample Collection<br>YYYY/MM/DD | 08 JAN 2014                             |
| Subject Number                          |   |
| Date of Birth                           | (b) (6)                                 |
| Gender                                  | Female <input checked="" type="radio"/> |
| Time of Sample Collection               | 11:42                                   |
| Analyte Name                            | LYMPHS                                  |
| Code                                    | 015123                                  |
| Result                                  | 33                                      |
| Unit                                    | %                                       |
| Lower limit                             | 14                                      |
| Upper limit                             | 46                                      |
| Flag                                    |   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (9)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:44**

**Generated On: 20 Jul 2016 11:47:42**

---

Clinically Significant? \_\_\_\_\_

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

00857100100

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (10)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:44**

**Generated On: 20 Jul 2016 11:47:42**

|   |   |
|---|---|
| Experiment Type                         | HEMATOLOGY                              |
| Date of Sample Collection<br>YYYY/MM/DD | 08 JAN 2014                             |
| Subject Number                          |   |
| Date of Birth                           | (b) (6)                                 |
| Gender                                  | Female <input checked="" type="radio"/> |
| Time of Sample Collection               | 11:42                                   |
| Analyte Name                            | MONOCYTES                               |
| Code                                    | 015131                                  |
| Result                                  | 8                                       |
| Unit                                    | %                                       |
| Lower limit                             | 4                                       |
| Upper limit                             | 12                                      |
| Flag                                    |   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (10)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:44**

**Generated On: 20 Jul 2016 11:47:42**

---

Clinically Significant? \_\_\_\_\_

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

00857100100

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (11)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:44**

**Generated On: 20 Jul 2016 11:47:42**

---

Experiment Type

HEMATOLOGY

---

Date of Sample Collection  
YYYY/MM/DD

08 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

11:42

---

Analyte Name

EOS

---

Code

015149

---

Result

3

---

Unit

%

---

Lower limit

0

---

Upper limit

5

---

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (11)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:44**

**Generated On: 20 Jul 2016 11:47:42**

---

Clinically Significant? \_\_\_\_\_

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

00857100100

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (12)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:44**

**Generated On: 20 Jul 2016 11:47:42**

|   |   |
|---|---|
| Experiment Type                         | HEMATOLOGY                              |
| Date of Sample Collection<br>YYYY/MM/DD | 08 JAN 2014                             |
| Subject Number                          |   |
| Date of Birth                           | (b) (6)                                 |
| Gender                                  | Female <input checked="" type="radio"/> |
| Time of Sample Collection               | 11:42                                   |
| Analyte Name                            | BASOS                                   |
| Code                                    | 015156                                  |
| Result                                  | 1                                       |
| Unit                                    | %                                       |
| Lower limit                             | 0                                       |
| Upper limit                             | 3                                       |
| Flag                                    |   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (12)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:44**

**Generated On: 20 Jul 2016 11:47:42**

---

Clinically Significant? \_\_\_\_\_

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

00857100100

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (13)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:44**

**Generated On: 20 Jul 2016 11:47:42**

---

Experiment Type

HEMATOLOGY

---

Date of Sample Collection  
YYYY/MM/DD

08 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

11:42

---

Analyte Name

PLATELETS

---

Code

015172

---

Result

250

---

Unit

X10E3/UL

---

Lower limit

155

---

Upper limit

379

---

Flag

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (13)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:44**

**Generated On: 20 Jul 2016 11:47:42**

---

Clinically Significant? \_\_\_\_\_

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

00857100100

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (14)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:44**

**Generated On: 20 Jul 2016 11:47:42**

---

Experiment Type

HEMATOLOGY

---

Date of Sample Collection  
YYYY/MM/DD

08 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

11:42

---

Analyte Name

NEUTROPHILS (ABSOLUTE)

---

Code

015909

---

Result

3.4

---

Unit

X10E3/UL

---

Lower limit

1.4

---

Upper limit

7.0

---

Flag

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (14)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:44**

**Generated On: 20 Jul 2016 11:47:42**

---

Clinically Significant? \_\_\_\_\_

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

00857100100

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (15)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:44**

**Generated On: 20 Jul 2016 11:47:42**

---

Experiment Type

HEMATOLOGY

---

Date of Sample Collection  
YYYY/MM/DD

08 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

11:42

---

Analyte Name

LYMPHS (ABSOLUTE)

---

Code

015917

---

Result

2.0

---

Unit

X10E3/UL

---

Lower limit

0.7

---

Upper limit

3.1

---

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (15)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:44**

**Generated On: 20 Jul 2016 11:47:42**

---

Clinically Significant? \_\_\_\_\_

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

00857100100

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (16)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:44**

**Generated On: 20 Jul 2016 11:47:42**

---

Experiment Type

HEMATOLOGY

---

Date of Sample Collection  
YYYY/MM/DD

08 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

11:42

---

Analyte Name

MONOCYTES(ABSOLUTE)

---

Code

015925

---

Result

0.5

---

Unit

X10E3/UL

---

Lower limit

0.1

---

Upper limit

0.9

---

Flag

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (16)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:44**

**Generated On: 20 Jul 2016 11:47:42**

---

Clinically Significant? \_\_\_\_\_

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

00857100100

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (17)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:44**

**Generated On: 20 Jul 2016 11:47:42**

|   |   |
|---|---|
| Experiment Type                         | HEMATOLOGY                              |
| Date of Sample Collection<br>YYYY/MM/DD | 08 JAN 2014                             |
| Subject Number                          |   |
| Date of Birth                           | (b) (6)                                 |
| Gender                                  | Female <input checked="" type="radio"/> |
| Time of Sample Collection               | 11:42                                   |
| Analyte Name                            | EOS (ABSOLUTE)                          |
| Code                                    | 015933                                  |
| Result                                  | 0.2                                     |
| Unit                                    | X10E3/UL                                |
| Lower limit                             | 0.0                                     |
| Upper limit                             | 0.4                                     |
| Flag                                    |   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (17)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:44**

**Generated On: 20 Jul 2016 11:47:42**

---

Clinically Significant? \_\_\_\_\_

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

00857100100

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (18)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:44**

**Generated On: 20 Jul 2016 11:47:42**

---

Experiment Type

HEMATOLOGY

---

Date of Sample Collection  
YYYY/MM/DD

08 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

11:42

---

Analyte Name

BASO (ABSOLUTE)

---

Code

015941

---

Result

0.1

---

Unit

X10E3/UL

---

Lower limit

0.0

---

Upper limit

0.2

---

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (18)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:44**

**Generated On: 20 Jul 2016 11:47:42**

---

Clinically Significant? \_\_\_\_\_

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

00857100100

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp URINALYSIS(8 JAN 2014)**

**Generated On: 20 Jul 2016 11:47:42**

---

Experiment Type

URINALYSIS

---

Date of Sample Collection  
YYYY/MM/DD

8 JAN 2014

---

Please document clinically relevant abnormalities in the AE form

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp URINALYSIS(8 JAN 2014)**

**Generated On: 20 Jul 2016 11:47:42**

---

Experiment Type

URINALYSIS

---

Date of Sample Collection  
YYYY/MM/DD

8 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

11:17

---

Analyte Name

SPECIFIC GRAVITY

---

Code

13060

---

Result

1.01

---

Unit

---

Lower limit

1.001

---

Upper limit

1.035

---

Flag

---

Clinically Significant?

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp URINALYSIS(8 JAN 2014)**

**Generated On: 20 Jul 2016 11:47:42**

---

Comment

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (2)**

**Generated On: 20 Jul 2016 11:47:42**

---

Experiment Type

URINALYSIS

---

Date of Sample Collection  
YYYY/MM/DD

8 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

11:17

---

Analyte Name

PH

---

Code

13078

---

Result

7

---

Unit

---

Lower limit

5

---

Upper limit

8

---

Flag

---

Clinically Significant?

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (2)**

**Generated On: 20 Jul 2016 11:47:42**

---

Comment

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (3)**

**Generated On: 20 Jul 2016 11:47:42**

---

Experiment Type

URINALYSIS

---

Date of Sample Collection  
YYYY/MM/DD

8 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

11:17

---

Analyte Name

GLUCOSE

---

Code

13086

---

Result

NORMAL

---

Unit

---

Lower limit

NORMAL

---

Upper limit

---

Flag

---

Clinically Significant?

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (3)**

**Generated On: 20 Jul 2016 11:47:42**

---

Comment

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (4)**

**Generated On: 20 Jul 2016 11:47:42**

---

Experiment Type

URINALYSIS

---

Date of Sample Collection  
YYYY/MM/DD

8 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

11:17

---

Analyte Name

PROTEIN

---

Code

13094

---

Result

NEGATIVE

---

Unit

---

Lower limit

NEGATIVE

---

Upper limit

---

Flag

---

Clinically Significant?

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (4)**

**Generated On: 20 Jul 2016 11:47:42**

---

Comment

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (5)**

**Generated On: 20 Jul 2016 11:47:42**

---

Experiment Type

URINALYSIS

---

Date of Sample Collection  
YYYY/MM/DD

8 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

11:17

---

Analyte Name

OCCULT BLOOD

---

Code

13102

---

Result

TRACE

---

Unit

---

Lower limit

NEGATIVE

---

Upper limit

---

Flag

High ☒

---

Clinically Significant?

---

PROD 04.000 (MAIN) RZ  
02APR2015 (807)

169 of 1716

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (5)**

**Generated On: 20 Jul 2016 11:47:42**

---

Comment

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (6)**

**Generated On: 20 Jul 2016 11:47:42**

---

Experiment Type

URINALYSIS

---

Date of Sample Collection  
YYYY/MM/DD

8 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

11:17

---

Analyte Name

BILIRUBIN

---

Code

13104

---

Result

NEGATIVE

---

Unit

---

Lower limit

NEGATIVE

---

Upper limit

---

Flag

---

Clinically Significant?



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (6)**

**Generated On: 20 Jul 2016 11:47:42**

---

Comment

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (7)**

**Generated On: 20 Jul 2016 11:47:42**

---

Experiment Type

URINALYSIS

---

Date of Sample Collection  
YYYY/MM/DD

8 JAN 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Female ☒

---

Time of Sample Collection

11:17

---

Analyte Name

NITRITE, URINE

---

Code

13106

---

Result

NEGATIVE

---

Unit

---

Lower limit

NEGATIVE

---

Upper limit

---

Flag

---

Clinically Significant?

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Lab-BU-LabCorp (7)**

**Generated On: 20 Jul 2016 11:47:42**

---

Comment

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: FTND Questionnaire**

**Generated On: 20 Jul 2016 11:47:42**

---

|      |      |
|------|------|
| Type | FTND |
|------|------|

---

|               |         |
|---------------|---------|
| Date of Birth | (b) (6) |
|---------------|---------|

---

|                    |             |
|--------------------|-------------|
| Date of assessment | 2014 JAN 08 |
| DD/MMM/YYYY        | DD/MMM/YYYY |

---

|                    |                        |
|--------------------|------------------------|
| Time of assessment | 12:46                  |
|                    | hour:min 24-hour clock |

---

|                   |  |
|-------------------|--|
| Assessment Status | Completed <input checked="" type="radio"/> |
|-------------------|--|

---

|  |   |
|--|---|
| 1. How soon after you wake up do you smoke your first cigarette? | 6-30 minutes <input checked="" type="radio"/> |
|--|---|

---

|  |                                     |
|--|-------------------------------------|
| 2. Do you find it difficult to refrain from smoking in places where it is forbidden? | No <input checked="" type="radio"/> |
|--|-------------------------------------|

---

|  |   |
|--|---|
| 3. Which cigarette would you hate most to give up? | The first in the morning <input checked="" type="radio"/> |
|--|---|

---

|  |  |
|--|--|
| 4. How many cigarettes per day do you smoke? | 11-20 <input checked="" type="radio"/> |
|--|--|

---

|   |                                      |
|---|--------------------------------------|
| 5. Do you smoke more frequently during the first hours after awakening than during the rest of the day? | Yes <input checked="" type="radio"/> |
|---|--------------------------------------|

---

|   |                                      |
|---|--------------------------------------|
| 6. Do you smoke even if you are so ill that you are in bed most of the day? | Yes <input checked="" type="radio"/> |
|---|--------------------------------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Screening**

**Form: Prochaska "Stage of Change" Questionnaire: Intention to Quit  
Smoking**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:38**

**Generated On: 20 Jul 2016 11:47:42**

---

Was paper questionnaire used? Yes ☒

---

Reason not done \_\_\_\_\_

---

Type PROCHASKA STAGE OF  
CHANGE QUESTIONNAIRE:  
INTENTION TO QUIT  
SMOKING

---

Date of assessment 08 JAN 2014  
DD/MMM/YYYY

---

Time of assessment 09:59  
hour:min 24-hour clock

---

1. Are you currently a smoker? Yes, I currently smoke ☒

---

2. In the last year, how many times have you quit  
smoking for at least 24 hours? 2

---

3. Are you seriously thinking of quitting smoking? No, not thinking of quitting ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Admission (Day -2)**

**Form: Date of Visit**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:11**

**Generated On: 20 Jul 2016 11:47:42**

---

Date of Visit

14 JAN 2014  
DD/MMM/YYYY

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Admission (Day -2)**

**Form: Inclusion Criteria**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:09**

**Generated On: 20 Jul 2016 11:47:42**

---

\*If any has been answered No, subject must not be included in the study.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Admission (Day -2)**

**Form: Inclusion Criteria (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:09**

**Generated On: 20 Jul 2016 11:47:42**

---

Inclusion Criterion Number

3

---

Inclusion Criterion

Smoking, apparently healthy subject as judged by the Investigator based on all available assessments from the Screening period/Day of Admission (e.g., safety laboratory, spirometry, vital signs, physical examination, ECG, chest X-ray, and medical history).

---

Result

Yes

---

\*If any has been answered No, subject must not be included in the study.

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Admission (Day -2)**

**Form: Inclusion Criteria (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:09**

**Generated On: 20 Jul 2016 11:47:42**

---

|                            |   |
|----------------------------|---|
| Inclusion Criterion Number | 4 |
|----------------------------|---|

---

|                     |   |
|---------------------|---|
| Inclusion Criterion | Subject smokes at least 10 commercially available mCCs per day (no brand restrictions), for the last 4 weeks, based on self-reporting. Furthermore, the subject has been smoking for at least the last 3 consecutive years. The smoking status will be verified based on a urinary cotinine test (cotinine $\geq$ 200 ng/mL). |
|---------------------|---|

---

|        |     |
|--------|-----|
| Result | Yes |
|--------|-----|

---

\*If any has been answered No, subject must not be included in the study.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Admission (Day -2)**

**Form: Inclusion Criteria (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:09**

**Generated On: 20 Jul 2016 11:47:42**

---

|                            |   |
|----------------------------|---|
| Inclusion Criterion Number | 5 |
|----------------------------|---|

---

|                     |  |
|---------------------|--|
| Inclusion Criterion | The subject does not plan to quit smoking within the next 6 months as assessed by the Prochaska 'Stage of Change' questionnaire. |
|---------------------|--|

---

|        |     |
|--------|-----|
| Result | Yes |
|--------|-----|

---

\*If any has been answered No, subject must not be included in the study.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Admission (Day -2)**

**Form: Inclusion Criteria (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:09**

**Generated On: 20 Jul 2016 11:47:42**

---

|                            |   |
|----------------------------|---|
| Inclusion Criterion Number | 6 |
|----------------------------|---|

---

|                     |  |                                  |
|---------------------|--|----------------------------------|
| Inclusion Criterion | The subject is ready to comply with study protocol (e.g readiness to accept interruptions of smoking for up to 91 days and to use THS 2.2 Menthol ). | <input checked="" type="radio"/> |
|---------------------|--|----------------------------------|

---

|        |     |                                  |
|--------|-----|----------------------------------|
| Result | Yes | <input checked="" type="radio"/> |
|--------|-----|----------------------------------|

---

\*If any has been answered No, subject must not be included in the study.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Admission (Day -2)**

**Form: Exclusion Criteria**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:07**

**Generated On: 20 Jul 2016 11:47:42**

---

\*If any has been answered Yes, subject must not be included in the study.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Admission (Day -2)**

**Form: Exclusion Criteria (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:07**

**Generated On: 20 Jul 2016 11:47:42**

---

|                            |   |
|----------------------------|---|
| Exclusion Criterion Number | 1 |
|----------------------------|---|

---

|                     |   |
|---------------------|---|
| Exclusion Criterion | As per Investigator judgment, the subject cannot participate in the study for any reason (e.g., medical, psychiatric and/or social reason). |
|---------------------|---|

---

|        |    |
|--------|----|
| Result | No |
|--------|----|

---

\*If any has been answered Yes, subject must not be included in the study.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Admission (Day -2)**

**Form: Exclusion Criteria (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:07**

**Generated On: 20 Jul 2016 11:47:42**

---

Exclusion Criterion Number

3

---

Exclusion Criterion

The subject has clinically relevant diseases which required medications (including but not limited to gastrointestinal, renal, hepatic, neurological, hematological, endocrine, oncological, urological, immunological, pulmonary, and cardiovascular disease or any other medical condition (including safety laboratory as per CTCAE), which in the opinion of the Investigator would jeopardize the safety of the subject.

---

Result

No

---

\*If any has been answered Yes, subject must not be included in the study.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Admission (Day -2)**

**Form: Exclusion Criteria (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:07**

**Generated On: 20 Jul 2016 11:47:42**

---

|                            |   |
|----------------------------|---|
| Exclusion Criterion Number | 7 |
|----------------------------|---|

---

|                     |   |
|---------------------|---|
| Exclusion Criterion | The subject has a body mass index (BMI) <18.5 or $\geq 35$ kg/m <sup>2</sup> . <input checked="" type="radio"/> |
|---------------------|---|

---

|        |                                     |
|--------|-------------------------------------|
| Result | No <input checked="" type="radio"/> |
|--------|-------------------------------------|

---

\*If any has been answered Yes, subject must not be included in the study.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Admission (Day -2)**

**Form: Exclusion Criteria (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:07**

**Generated On: 20 Jul 2016 11:47:42**

---

|                            |   |
|----------------------------|---|
| Exclusion Criterion Number | 8 |
|----------------------------|---|

---

|                     |   |
|---------------------|---|
| Exclusion Criterion | As per Investigator judgment, the subject has medical conditions which require or will require in the course of the study, a medical intervention (e.g., start of treatment, surgery, hospitalization) which may interfere with the study participation and/or study results. |
|---------------------|---|

---

|        |    |
|--------|----|
| Result | No |
|--------|----|

---

\*If any has been answered Yes, subject must not be included in the study.

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Admission (Day -2)**

**Form: Exclusion Criteria (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:07**

**Generated On: 20 Jul 2016 11:47:42**

---

|                            |   |
|----------------------------|---|
| Exclusion Criterion Number | 9 |
|----------------------------|---|

---

|                     |  |
|---------------------|--|
| Exclusion Criterion | Any subject with an history of adverse events linked to caffeine or caffeine containing drugs (e.g., Vivarin), such as but not limited to hypersensitivity or allergy. |
|---------------------|--|

---

|        |    |
|--------|----|
| Result | No |
|--------|----|

---

\*If any has been answered Yes, subject must not be included in the study.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Admission (Day -2)**

**Form: Exclusion Criteria (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:07**

**Generated On: 20 Jul 2016 11:47:42**

---

|                            |    |
|----------------------------|----|
| Exclusion Criterion Number | 10 |
|----------------------------|----|

---

|                     |   |
|---------------------|---|
| Exclusion Criterion | The subject has used nicotine-containing products other than commercially available mCC (either tobacco-based products or NRT), as well as electronic cigarettes and similar devices, within 4 weeks prior to assessment. |
|---------------------|---|

---

|        |    |
|--------|----|
| Result | No |
|--------|----|

---

\*If any has been answered Yes, subject must not be included in the study.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Admission (Day -2)**

**Form: Exclusion Criteria (7)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:07**

**Generated On: 20 Jul 2016 11:47:42**

---

|                            |    |
|----------------------------|----|
| Exclusion Criterion Number | 11 |
|----------------------------|----|

---

|                     |  |
|---------------------|--|
| Exclusion Criterion | The subject has received medication (prescription or over-the-counter) within 14 days or within five half-lives of the drug (whichever is longer) prior to the Admission Day (Day -2), which has an impact on CYP1A2 or CYP2A6 activity. |
|---------------------|--|

---

|        |    |
|--------|----|
| Result | No |
|--------|----|

---

\*If any has been answered Yes, subject must not be included in the study.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Admission (Day -2)**

**Form: Exclusion Criteria (8)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:07**

**Generated On: 20 Jul 2016 11:47:42**

---

|                            |    |
|----------------------------|----|
| Exclusion Criterion Number | 12 |
|----------------------------|----|

---

|                     |  |
|---------------------|--|
| Exclusion Criterion | If a subject has received any medication (prescribed or over-the-counter) within 14 days prior to Screening or prior to the Admission Day (Day -2), it will be decided at the discretion of the Investigator if these can potentially interfere with the study objectives or subject's safety. |
|---------------------|--|

---

|        |    |
|--------|----|
| Result | No |
|--------|----|

---

\*If any has been answered Yes, subject must not be included in the study.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Admission (Day -2)**

**Form: Exclusion Criteria (9)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:07**

**Generated On: 20 Jul 2016 11:47:42**

---

|                            |    |
|----------------------------|----|
| Exclusion Criterion Number | 13 |
|----------------------------|----|

---

|                     |   |
|---------------------|---|
| Exclusion Criterion | Concomitant use of<br>nonsteroidal<br>anti-inflammatory drugs<br>(NSAIDs) or acetylsalicylic<br>acid. |
|---------------------|---|

---

|        |                                     |
|--------|-------------------------------------|
| Result | No <input checked="" type="radio"/> |
|--------|-------------------------------------|

---

\*If any has been answered Yes, subject must not be included in the study.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Admission (Day -2)**

**Form: Exclusion Criteria (10)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:07**

**Generated On: 20 Jul 2016 11:47:42**

---

|                            |    |
|----------------------------|----|
| Exclusion Criterion Number | 14 |
|----------------------------|----|

---

|                     |   |
|---------------------|---|
| Exclusion Criterion | The subject has a positive alcohol test and/or the subject has a history of alcohol abuse that could interfere with the subject's participation in the study. |
|---------------------|---|

---

|        |    |
|--------|----|
| Result | No |
|--------|----|

---

\*If any has been answered Yes, subject must not be included in the study.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Admission (Day -2)**

**Form: Exclusion Criteria (11)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:07**

**Generated On: 20 Jul 2016 11:47:42**

---

|                            |    |
|----------------------------|----|
| Exclusion Criterion Number | 15 |
|----------------------------|----|

---

|                     |  |
|---------------------|--|
| Exclusion Criterion | The subject has a positive urine drug test. <input checked="" type="radio"/> |
|---------------------|--|

---

|        |                          |
|--------|--------------------------|
| Result | No <input type="radio"/> |
|--------|--------------------------|

---

\*If any has been answered Yes, subject must not be included in the study.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Admission (Day -2)**

**Form: Exclusion Criteria (12)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:07**

**Generated On: 20 Jul 2016 11:47:42**

---

|                            |    |
|----------------------------|----|
| Exclusion Criterion Number | 17 |
|----------------------------|----|

---

|                     |  |                                  |
|---------------------|--|----------------------------------|
| Exclusion Criterion | Donation or receipt of whole blood or blood products within 3 months prior to Admission. | <input checked="" type="radio"/> |
|---------------------|--|----------------------------------|

---

|        |    |                                  |
|--------|----|----------------------------------|
| Result | No | <input checked="" type="radio"/> |
|--------|----|----------------------------------|

---

\*If any has been answered Yes, subject must not be included in the study.

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Admission (Day -2)**

**Form: Exclusion Criteria (13)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:07**

**Generated On: 20 Jul 2016 11:47:42**

---

|                            |    |
|----------------------------|----|
| Exclusion Criterion Number | 21 |
|----------------------------|----|

---

|                     |  |
|---------------------|--|
| Exclusion Criterion | For women only: Subject is pregnant (does not have negative pregnancy tests at Screening and at Admission) or is breast feeding. |
|---------------------|--|

---

|        |    |
|--------|----|
| Result | No |
|--------|----|

---

\*If any has been answered Yes, subject must not be included in the study.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Admission (Day -2)**

**Form: Exclusion Criteria (14)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:07**

**Generated On: 20 Jul 2016 11:47:42**

---

|                            |    |
|----------------------------|----|
| Exclusion Criterion Number | 22 |
|----------------------------|----|

---

|                     |   |
|---------------------|---|
| Exclusion Criterion | For women only : Subject<br>does not agree to use an<br>acceptable method of<br>effective contraception |
|---------------------|---|

---

|        |    |
|--------|----|
| Result | No |
|--------|----|

---

\*If any has been answered Yes, subject must not be included in the study.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Admission (Day -2)**

**Form: Vital Signs**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:12**

**Generated On: 20 Jul 2016 11:47:42**

---

Were Vitals Signs assessed? Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

Has the subject smoked within 15 minutes prior to assessment No ☒

---

Time of assessment 15:21  
hour:min 24-hour clock

---

Pulse rate 99  
beats per minute

---

Respiratory rate 16  
breaths per minute

---

Blood Pressure (systolic) 119  
mmHg

---

Blood Pressure (diastolic) 81  
mmHg

---

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Admission (Day -2)**

**Form: Product preference**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:11**

**Generated On: 20 Jul 2016 11:47:42**

---

Which Product Arm would you prefer to be randomized  
to:

THS 2.2 menthol ☒

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Admission (Day -2)**

**Form: Advice on the risk of smoking and debriefing**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:11**

**Generated On: 20 Jul 2016 11:47:42**

---

Has the subject received advices on the risks of  
smoking?

Yes ☒

---

Has a debriefing been performed about THS 2.2?

Yes ☒

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Admission (Day -2)**

**Form: Physical Examination**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:09**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed?

Yes ☒

---

If No, please specify the reason:

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Admission (Day -2)**

**Form: Physical Examination (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:09**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed? Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

System General Appearance ☒

---

Outcome Normal ☒

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done False

---

Not Done; please specify the reason: \_\_\_\_\_

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Admission (Day -2)**

**Form: Physical Examination (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:09**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed? Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

System ☒ HEENT  
(head, eyes, ears, nose,  
throat)

---

Outcome ☒ Normal

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done ☐ False

---

Not Done; please specify the reason: \_\_\_\_\_

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Admission (Day -2)**

**Form: Physical Examination (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:09**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed? Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

System Thyroid Gland ☒

---

Outcome Normal ☒

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done False

---

Not Done; please specify the reason: \_\_\_\_\_

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Admission (Day -2)**

**Form: Physical Examination (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:09**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed? Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

System Heart ☒

---

Outcome Normal ☒

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done False

---

Not Done; please specify the reason: \_\_\_\_\_

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Admission (Day -2)**

**Form: Physical Examination (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:09**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed? Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

System Chest ☒

---

Outcome Normal ☒

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done False

---

Not Done; please specify the reason: \_\_\_\_\_

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Admission (Day -2)**

**Form: Physical Examination (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:09**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed? Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

System Lungs ☒

---

Outcome Normal ☒

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done False

---

Not Done; please specify the reason: \_\_\_\_\_

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Admission (Day -2)**

**Form: Physical Examination (7)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:09**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed? Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

System Gastrointestinal ☒

---

Outcome Normal ☒

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done False

---

Not Done; please specify the reason: \_\_\_\_\_

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Admission (Day -2)**

**Form: Physical Examination (8)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:09**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed? Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

System Cardiovascular System ☒

---

Outcome Normal ☒

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done False

---

Not Done; please specify the reason: \_\_\_\_\_

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Admission (Day -2)**

**Form: Physical Examination (9)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:09**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed? Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

System Neurologic ☒

---

Outcome Normal ☒

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done False

---

Not Done; please specify the reason: \_\_\_\_\_

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Admission (Day -2)**

**Form: Physical Examination (10)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:09**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed? Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

System Skin ☒

---

Outcome Normal ☒

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done False

---

Not Done; please specify the reason: \_\_\_\_\_



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Admission (Day -2)**

**Form: Physical Examination (11)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:09**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed? Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

System Back ☒

---

Outcome Normal ☒

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done False

---

Not Done; please specify the reason: \_\_\_\_\_

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Admission (Day -2)**

**Form: Physical Examination (12)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:09**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed? Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

System Musculoskeletal ☒

---

Outcome Normal ☒

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done False

---

Not Done; please specify the reason: \_\_\_\_\_

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Admission (Day -2)**

**Form: Physical Examination (13)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:09**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed? Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

System Abdomen ☒

---

Outcome Normal ☒

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done False

---

Not Done; please specify the reason: \_\_\_\_\_

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Admission (Day -2)**

**Form: Physical Examination (14)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:09**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed? Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

System Dentition ☒

---

Outcome Normal ☒

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done False

---

Not Done; please specify the reason: \_\_\_\_\_

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Admission (Day -2)**

**Form: Physical Examination (15)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:09**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed?

Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

System

Other ☒

---

Other, Specify \_\_\_\_\_

---

Outcome \_\_\_\_\_

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done

True

---

Not Done; please specify the reason: \_\_\_\_\_

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Admission (Day -2)**

**Form: Physical Examination (16)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:09**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed? Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

System Other ☒

---

Other, Specify \_\_\_\_\_

---

Outcome \_\_\_\_\_

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done True

---

Not Done; please specify the reason: NOT EXAMINED

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Admission (Day -2)**

**Form: Physical Examination (17)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:09**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed?

Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

System

Other ☒

---

Other, Specify \_\_\_\_\_

---

Outcome \_\_\_\_\_

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done

True

---

Not Done; please specify the reason: \_\_\_\_\_

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Admission (Day -2)**

**Form: Physical Examination (18)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:09**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed?

Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

System

Other ☒

---

Other, Specify \_\_\_\_\_

---

Outcome \_\_\_\_\_

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done

True

---

Not Done; please specify the reason: \_\_\_\_\_

NOT EXAMINED



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Admission (Day -2)**

**Form: Physical Examination (19)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:09**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed?

Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

System

Other ☒

---

Other, Specify \_\_\_\_\_

---

Outcome \_\_\_\_\_

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done

True

---

Not Done; please specify the reason: \_\_\_\_\_

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Admission (Day -2)**

**Form: Identification of Current Cigarette Brand**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:11**

**Generated On: 20 Jul 2016 11:47:42**

---

Brand name

305 MENTHOL 100'S

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Admission (Day -2)**

**Form: THS 2.2 menthol product test**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:11**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the THS 2.2 menthol product trial performed?

Yes ☒

---

If the THS 2.2 menthol product trial was not performed,  
please explain

---

How many THS 2.2 menthol tobacco sticks did the  
subject use on this day?

2

---

Is the subject willing and able to use the product during  
the study?

Yes ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Admission (Day -2)**

**Form: Smoking History**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:11**

**Generated On: 20 Jul 2016 11:47:42**

---

2. Did the subject smoke for at least 3 consecutive years? Yes ☐

---

3. How many menthol cigarettes per day has the subject smoked on average during the last 4 weeks? 10 to 19 ☐

---

4. Did the subject smoke menthol cigarettes in the last 4 weeks? Yes ☐

---

5. The subject has used nicotine-containing products other than commercially available mCC (either tobacco-based products or nicotine-replacement therapy [NRT]), electronic cigarettes and similar devices, within 4 weeks prior to assessment. No ☐

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Admission (Day -2)**

**Form: Weight**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:12**

**Generated On: 20 Jul 2016 11:47:42**

---

Measurement(s) assessed?

Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

Time of assessment

15:05  
hour:min 24-hour clock

---

Weight

67.0  
kg

---

Waist circumference

84  
cm

---

BMI

24.2

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Admission (Day -2)**

**Form: Urine Drug Screen**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:09**

**Generated On: 20 Jul 2016 11:47:42**

---

|           |       |
|-----------|-------|
| Not Done? | False |
|-----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                           |                        |
|---------------------------|------------------------|
| Time of sample collection | 15:03                  |
|                           | hour:min 24-hour clock |

---

| Drug type       | Result   |
|-----------------|----------|
| Amphetamines    | Negative |
| Barbiturates    | Negative |
| Benzodiazepines | Negative |
| Cannabinoids    | Negative |
| Cocaine         | Negative |

---

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Admission (Day -2)**

**Form: Urine Drug Screen (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:09**

**Generated On: 20 Jul 2016 11:47:42**

---

| Drug type | Result   |
|-----------|----------|
| Opiates   | Negative |

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Admission (Day -2)**

**Form: Alcohol Test**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:09**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the alcohol test performed? Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

Method used Breath test ☒

---

Time of assessment 14:50  
hour:min 24-hour clock

---

Result Negative ☒

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Admission (Day -2)**

**Form: Urine Pregnancy Test**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

If Not Done, specify reason

---

---

|              |                        |
|--------------|------------------------|
| Time of Test | 15:14                  |
|              | hour:min 24-hour clock |

---

---

|                |   |
|----------------|---|
| Specify result | Negative <input checked="" type="radio"/> |
|----------------|---|

---

If unclear, please confirm with FSH test

---

Specify result of FSH test

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Admission (Day -2)**

**Form: CO Breath Test**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:07**

**Generated On: 20 Jul 2016 11:47:42**

---

|                     |       |
|---------------------|-------|
| Assessment not done | False |
|---------------------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                           |                        |
|---------------------------|------------------------|
| Actual Time of Assessment | 14:49                  |
|                           | hour:min 24-hour clock |

---

|        |     |
|--------|-----|
| Result | 35  |
|        | ppm |

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Admission (Day -2)**

**Form: Prochaska "Stage of Change" Questionnaire: Intention to Quit  
Smoking**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:11**

**Generated On: 20 Jul 2016 11:47:42**

---

Was paper questionnaire used? Yes ☒

---

Reason not done \_\_\_\_\_

---

Type PROCHASKA STAGE OF  
CHANGE QUESTIONNAIRE:  
INTENTION TO QUIT  
SMOKING

---

Date of assessment 14 JAN 2014  
DD/MMM/YYYY

---

Time of assessment 15:53  
hour:min 24-hour clock

---

1. Are you currently a smoker? Yes, I currently smoke ☒

---

2. In the last year, how many times have you quit  
smoking for at least 24 hours? 2

---

3. Are you seriously thinking of quitting smoking? No, not thinking of quitting ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Date of Visit**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:15**

**Generated On: 20 Jul 2016 11:47:42**

---

Date of Visit

15 JAN 2014  
DD/MMM/YYYY

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Vital Signs**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:15**

**Generated On: 20 Jul 2016 11:47:42**

---

Were Vitals Signs assessed?

Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

Has the subject smoked within 15 minutes prior to  
assessment

No ☒

---

Time of assessment

09:43  
hour:min 24-hour clock

---

Pulse rate

83  
beats per minute

---

Respiratory rate

20  
breaths per minute

---

Blood Pressure (systolic)

115  
mmHg

---

Blood Pressure (diastolic)

76  
mmHg

---

Vital Signs Position of Subject

Supine ☒

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: CoHb Blood Sample**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:12**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 15 JAN 2014 |
|---------------------|-------------|

---

|           |  |
|-----------|--|
| Timepoint | 20:00 - 21:30 <input checked="" type="radio"/> |
|-----------|--|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 20:46 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: CO Breath Test (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:12**

**Generated On: 20 Jul 2016 11:47:42**

---

|                     |       |
|---------------------|-------|
| Assessment not done | False |
|---------------------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                |   |
|----------------|---|
| Scheduled Time | Within 15 min prior to smoking <input checked="" type="radio"/> |
|----------------|---|

---

|   |       |
|---|-------|
| Actual Time of Assessment<br>hour:min 24-hour clock | 06:55 |
|---|-------|

---

|             |    |
|-------------|----|
| Result(ppm) | 10 |
|-------------|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: CO Breath Test (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:12**

**Generated On: 20 Jul 2016 11:47:42**

---

|                     |       |
|---------------------|-------|
| Assessment not done | False |
|---------------------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                |  |
|----------------|--|
| Scheduled Time | 12:00 - 13:30 <input checked="" type="radio"/> |
|----------------|--|

---

|   |       |
|---|-------|
| Actual Time of Assessment<br>hour:min 24-hour clock | 12:11 |
|---|-------|

---

|             |    |
|-------------|----|
| Result(ppm) | 22 |
|-------------|----|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: CO Breath Test (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:12**

**Generated On: 20 Jul 2016 11:47:42**

---

|                     |       |
|---------------------|-------|
| Assessment not done | False |
|---------------------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                |  |
|----------------|--|
| Scheduled Time | 16:00 - 17:30 <input checked="" type="radio"/> |
|----------------|--|

---

|   |       |
|---|-------|
| Actual Time of Assessment<br>hour:min 24-hour clock | 16:10 |
|---|-------|

---

|             |    |
|-------------|----|
| Result(ppm) | 18 |
|-------------|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: CO Breath Test (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:12**

**Generated On: 20 Jul 2016 11:47:42**

---

|                     |       |
|---------------------|-------|
| Assessment not done | False |
|---------------------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                |  |
|----------------|--|
| Scheduled Time | 20:00 - 21:30 <input checked="" type="radio"/> |
|----------------|--|

---

|   |       |
|---|-------|
| Actual Time of Assessment<br>hour:min 24-hour clock | 20:17 |
|---|-------|

---

|             |    |
|-------------|----|
| Result(ppm) | 20 |
|-------------|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: 4 hour urine collection**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:14**

**Generated On: 20 Jul 2016 11:47:42**

---

|            |                        |
|------------|------------------------|
| Start Time | 10:03                  |
|            | hour:min 24-hour clock |

---

|          |                        |
|----------|------------------------|
| End Time | 14:00                  |
|          | hour:min 24-hour clock |

---

|        |     |
|--------|-----|
| Volume | 293 |
|        | mL  |

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Sample Urine Collection (4 Hour collection)**

**Generated On: 20 Jul 2016 11:47:42**

---

Were samples for 4h collected? Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

How many primary tubes were collected? 11

---

How many back up tubes were collected? 15

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Lab\_BU\_COHB (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:15**

**Generated On: 20 Jul 2016 11:47:42**

|                               |                       |
|-------------------------------|-----------------------|
| Sample Barcode                | 05115150000097        |
| Analyte                       | CARBOXYHEMOGLOBIN     |
| Sample type                   | BLOOD                 |
| Result                        | .                     |
| Result Unit                   | %                     |
| Lab Status                    | OTHER                 |
| Sample comment                | ANALYSIS NOT REQUIRED |
| Detection method              | SPECTROPHOTOMETRIC    |
| Lower limit of quantification | 0.500                 |
| Planned time point (Hour)     | 20                    |
| Day of Visit                  | -1                    |
| Celerion Study Number         | AA99128-16            |
| Date of Collection            | 2014-JAN-15           |
| Timepoint-minutes             |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Lab\_BU\_COHB (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:15**

**Generated On: 20 Jul 2016 11:47:42**

---

Start Day (24 hour urine only)

---

End Day (24 hour Urine Only)

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:15**

**Generated On: 20 Jul 2016 11:47:42**

Date of Birth

(b) (6)

Date of assessment

2014 JAN 15

DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

20:40

hour:min 24-hour clock

Assessment Status

Completed

1. Was smoking satisfying?

Moderately

2. Did cigarettes taste good?

Moderately

3. Did you enjoy the sensation in your throat and chest?

Very little

4. Did smoking calm you down?

Very little

5. Did smoking make you feel more awake?

Moderately

6. Did smoking make you feel less irritable?

Very little

7. Did smoking help you concentrate?

Very little

8. Did smoking reduce your hunger for food?

Moderately

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:15**

**Generated On: 20 Jul 2016 11:47:42**

---

9. Did smoking make you dizzy? Very little ☐

---

10. Did smoking make you nauseous? Not at all ☐

---

11. Did smoking immediately relieve your craving for a  
cigarette? Moderately ☐

---

12. Did you enjoy smoking? Moderately ☐

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Behavioral Risk Factor Surveillance System Questionnaire**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:12**

**Generated On: 20 Jul 2016 11:47:42**

---

|      |  |
|------|--|
| Type | BEHAVIORAL RISK FACTOR<br>SURVEILLANCE SYSTEM<br>QUESTIONNAIRE |
|------|--|

---

|                               |                           |
|-------------------------------|---------------------------|
| Was paper questionnaire used? | Yes <input type="radio"/> |
|-------------------------------|---------------------------|

---

|                 |       |
|-----------------|-------|
| Reason not done | <hr/> |
|-----------------|-------|

---

|                    |                            |
|--------------------|----------------------------|
| Date of assessment | 15 JAN 2014<br>DD/MMM/YYYY |
|--------------------|----------------------------|

---

|                    |                                 |
|--------------------|---------------------------------|
| Time of assessment | 20:42<br>hour:min 24-hour clock |
|--------------------|---------------------------------|

---

|   |                           |
|---|---------------------------|
| Have you ever smoked 100 cigarettes or more in your life? | Yes <input type="radio"/> |
|---|---------------------------|

---

|  |                                 |
|--|---------------------------------|
| Do you now smoke cigarettes every day, some days, or not at all? | Every day <input type="radio"/> |
|--|---------------------------------|

---

|  |                          |
|--|--------------------------|
| During the past 12 months, have you stopped smoking for one day or longer because you were trying to quit smoking? | No <input type="radio"/> |
|--|--------------------------|

---

|  |       |
|--|-------|
| How long has it been since you last smoked a cigarette, even one or two puffs? | <hr/> |
|--|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Behavioral Risk Factor Surveillance System Questionnaire**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:12**

**Generated On: 20 Jul 2016 11:47:42**

---

Do you currently use chewing tobacco, snuff, or snus  
every day, some days, or not at all?

Not at all ☐

NOTE: Snus (Swedish for snuff) is a moist smokeless  
tobacco, usually sold in small pouches that are placed  
under the lip against the gum.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:12**

**Generated On: 20 Jul 2016 11:47:42**

---

|      |                       |
|------|-----------------------|
| Type | SMOKING QUESTIONNAIRE |
|------|-----------------------|

---

|                               |                           |
|-------------------------------|---------------------------|
| Was paper questionnaire used? | Yes <input type="radio"/> |
|-------------------------------|---------------------------|

---

|                 |       |
|-----------------|-------|
| Reason not done | <hr/> |
|-----------------|-------|

---

|                    |                            |
|--------------------|----------------------------|
| Date of assessment | 15 JAN 2014<br>DD/MMM/YYYY |
|--------------------|----------------------------|

---

|                    |                                 |
|--------------------|---------------------------------|
| Time of assessment | 20:52<br>hour:min 24-hour clock |
|--------------------|---------------------------------|

---

|  |   |
|--|---|
| 1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)? | Daily smoker (at least one cigarette per day, disregarding religious fasting) <input type="radio"/> |
|--|---|

---

|  |                           |
|--|---------------------------|
| 2. Have you ever smoked 100 cigarettes or more in your life? | Yes <input type="radio"/> |
|--|---------------------------|

---

|  |                           |
|--|---------------------------|
| 3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day? | Yes <input type="radio"/> |
|--|---------------------------|

---

|   |          |
|---|----------|
| 4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly? | 22 Years |
|---|----------|

---

|   |  |
|---|--|
| 5. If you are an ex-smoker of cigarettes: For how long have you quit now? |  |
|---|--|

---

|       |       |
|-------|-------|
| Years | <hr/> |
|-------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:12**

**Generated On: 20 Jul 2016 11:47:42**

---

Months

---

Days

---

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?  
(Please add together any separate periods of quitting)

---

Years

---

Months

---

Days

---

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking?

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:12**

**Generated On: 20 Jul 2016 11:47:42**

---

|      |                       |
|------|-----------------------|
| Type | SMOKING QUESTIONNAIRE |
|------|-----------------------|

---

|                               |                           |
|-------------------------------|---------------------------|
| Was paper questionnaire used? | Yes <input type="radio"/> |
|-------------------------------|---------------------------|

---

|                 |       |
|-----------------|-------|
| Reason not done | <hr/> |
|-----------------|-------|

---

|                    |                            |
|--------------------|----------------------------|
| Date of assessment | 15 JAN 2014<br>DD/MMM/YYYY |
|--------------------|----------------------------|

---

|                    |                                 |
|--------------------|---------------------------------|
| Time of assessment | 20:52<br>hour:min 24-hour clock |
|--------------------|---------------------------------|

---

|  |   |
|--|---|
| 1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)? | Daily smoker (at least one cigarette per day, disregarding religious fasting) <input type="radio"/> |
|--|---|

---

|  |                           |
|--|---------------------------|
| 2. Have you ever smoked 100 cigarettes or more in your life? | Yes <input type="radio"/> |
|--|---------------------------|

---

|  |                           |
|--|---------------------------|
| 3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day? | Yes <input type="radio"/> |
|--|---------------------------|

---

|   |          |
|---|----------|
| 4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly? | 22 Years |
|---|----------|

---

|   |  |
|---|--|
| 5. If you are an ex-smoker of cigarettes: For how long have you quit now? |  |
|---|--|

---

|       |       |
|-------|-------|
| Years | <hr/> |
|-------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:12**

**Generated On: 20 Jul 2016 11:47:42**

---

Months

---

---

Days

---

---

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?  
(Please add together any separate periods of quitting)

---

Years

---

Months

---

Days

---

---

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking?

---

Time

Currently (last 3 months) ☒

---

8. On average, how many Manufactured cigarettes  
do/did you smoke per day?

---

Manufactured Cigarettes  
per day

10

---

8. On average, how many Hand-rolled Cigarettes do/did  
you smoke per day?

---

None ☒

Hand-rolled Cigarettes  
per day

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:12**

**Generated On: 20 Jul 2016 11:47:42**

---

8. On average, how many cigars do/did you smoke per  
day?

None ☐

---

Cigars  
per day

---

8. On average, how many pipes do/did you smoke per  
day?

None ☐

---

Pipes  
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:12**

**Generated On: 20 Jul 2016 11:47:42**

---

|      |                       |
|------|-----------------------|
| Type | SMOKING QUESTIONNAIRE |
|------|-----------------------|

---

|                               |                           |
|-------------------------------|---------------------------|
| Was paper questionnaire used? | Yes <input type="radio"/> |
|-------------------------------|---------------------------|

---

|                 |       |
|-----------------|-------|
| Reason not done | <hr/> |
|-----------------|-------|

---

|                    |                            |
|--------------------|----------------------------|
| Date of assessment | 15 JAN 2014<br>DD/MMM/YYYY |
|--------------------|----------------------------|

---

|                    |                                 |
|--------------------|---------------------------------|
| Time of assessment | 20:52<br>hour:min 24-hour clock |
|--------------------|---------------------------------|

---

|  |   |
|--|---|
| 1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)? | Daily smoker (at least one cigarette per day, disregarding religious fasting) <input type="radio"/> |
|--|---|

---

|  |                           |
|--|---------------------------|
| 2. Have you ever smoked 100 cigarettes or more in your life? | Yes <input type="radio"/> |
|--|---------------------------|

---

|  |                           |
|--|---------------------------|
| 3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day? | Yes <input type="radio"/> |
|--|---------------------------|

---

|   |          |
|---|----------|
| 4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly? | 22 Years |
|---|----------|

---

|   |  |
|---|--|
| 5. If you are an ex-smoker of cigarettes: For how long have you quit now? |  |
|---|--|

---

|       |       |
|-------|-------|
| Years | <hr/> |
|-------|-------|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:12**

**Generated On: 20 Jul 2016 11:47:42**

---

Months

---

---

Days

---

---

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?  
(Please add together any separate periods of quitting)

---

Years

---

Months

---

Days

---

---

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking?

---

Time

1 year ago ☒

---

8. On average, how many Manufactured cigarettes  
do/did you smoke per day?

---

Manufactured Cigarettes  
per day

10

---

8. On average, how many Hand-rolled Cigarettes do/did  
you smoke per day?

---

None ☒

Hand-rolled Cigarettes  
per day

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:12**

**Generated On: 20 Jul 2016 11:47:42**

---

8. On average, how many cigars do/did you smoke per  
day?

None ☐

---

Cigars  
per day

---

8. On average, how many pipes do/did you smoke per  
day?

None ☐

---

Pipes  
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:12**

**Generated On: 20 Jul 2016 11:47:42**

---

|      |                       |
|------|-----------------------|
| Type | SMOKING QUESTIONNAIRE |
|------|-----------------------|

---

|                               |                           |
|-------------------------------|---------------------------|
| Was paper questionnaire used? | Yes <input type="radio"/> |
|-------------------------------|---------------------------|

---

|                 |       |
|-----------------|-------|
| Reason not done | <hr/> |
|-----------------|-------|

---

|                    |                            |
|--------------------|----------------------------|
| Date of assessment | 15 JAN 2014<br>DD/MMM/YYYY |
|--------------------|----------------------------|

---

|                    |                                 |
|--------------------|---------------------------------|
| Time of assessment | 20:52<br>hour:min 24-hour clock |
|--------------------|---------------------------------|

---

|  |   |
|--|---|
| 1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)? | Daily smoker (at least one cigarette per day, disregarding religious fasting) <input type="radio"/> |
|--|---|

---

|  |                           |
|--|---------------------------|
| 2. Have you ever smoked 100 cigarettes or more in your life? | Yes <input type="radio"/> |
|--|---------------------------|

---

|  |                           |
|--|---------------------------|
| 3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day? | Yes <input type="radio"/> |
|--|---------------------------|

---

|   |          |
|---|----------|
| 4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly? | 22 Years |
|---|----------|

---

|   |  |
|---|--|
| 5. If you are an ex-smoker of cigarettes: For how long have you quit now? |  |
|---|--|

---

|       |       |
|-------|-------|
| Years | <hr/> |
|-------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:12**

**Generated On: 20 Jul 2016 11:47:42**

---

Months \_\_\_\_\_

---

Days \_\_\_\_\_

---

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?  
(Please add together any separate periods of quitting)

---

Years \_\_\_\_\_

---

Months \_\_\_\_\_

---

Days \_\_\_\_\_

---

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking?

---

Time

5 years ago ☒

---

8. On average, how many Manufactured cigarettes do/did you smoke per day?

---

Manufactured Cigarettes  
per day

10

---

8. On average, how many Hand-rolled Cigarettes do/did you smoke per day?

---

None ☒

---

Hand-rolled Cigarettes  
per day \_\_\_\_\_

---

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:12**

**Generated On: 20 Jul 2016 11:47:42**

---

8. On average, how many cigars do/did you smoke per  
day?

None ☐

---

Cigars  
per day

---

8. On average, how many pipes do/did you smoke per  
day?

None ☐

---

Pipes  
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:12**

**Generated On: 20 Jul 2016 11:47:42**

---

|      |                       |
|------|-----------------------|
| Type | SMOKING QUESTIONNAIRE |
|------|-----------------------|

---

|                               |                           |
|-------------------------------|---------------------------|
| Was paper questionnaire used? | Yes <input type="radio"/> |
|-------------------------------|---------------------------|

---

|                 |       |
|-----------------|-------|
| Reason not done | <hr/> |
|-----------------|-------|

---

|                    |                            |
|--------------------|----------------------------|
| Date of assessment | 15 JAN 2014<br>DD/MMM/YYYY |
|--------------------|----------------------------|

---

|                    |                                 |
|--------------------|---------------------------------|
| Time of assessment | 20:52<br>hour:min 24-hour clock |
|--------------------|---------------------------------|

---

|  |   |
|--|---|
| 1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)? | Daily smoker (at least one cigarette per day, disregarding religious fasting) <input type="radio"/> |
|--|---|

---

|  |                           |
|--|---------------------------|
| 2. Have you ever smoked 100 cigarettes or more in your life? | Yes <input type="radio"/> |
|--|---------------------------|

---

|  |                           |
|--|---------------------------|
| 3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day? | Yes <input type="radio"/> |
|--|---------------------------|

---

|   |          |
|---|----------|
| 4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly? | 22 Years |
|---|----------|

---

|   |  |
|---|--|
| 5. If you are an ex-smoker of cigarettes: For how long have you quit now? |  |
|---|--|

---

|       |       |
|-------|-------|
| Years | <hr/> |
|-------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:12**

**Generated On: 20 Jul 2016 11:47:42**

---

Months \_\_\_\_\_

---

Days \_\_\_\_\_

---

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?  
(Please add together any separate periods of quitting)

---

Years \_\_\_\_\_

---

Months \_\_\_\_\_

---

Days \_\_\_\_\_

---

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking?

---

Time

10 years ago ☒

---

8. On average, how many Manufactured cigarettes do/did you smoke per day?

---

Manufactured Cigarettes  
per day

10

---

8. On average, how many Hand-rolled Cigarettes do/did you smoke per day?

---

None ☒

---

Hand-rolled Cigarettes  
per day

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:12**

**Generated On: 20 Jul 2016 11:47:42**

---

8. On average, how many cigars do/did you smoke per  
day?

None ☐

---

Cigars  
per day

---

8. On average, how many pipes do/did you smoke per  
day?

None ☐

---

Pipes  
per day



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:12**

**Generated On: 20 Jul 2016 11:47:42**

---

|      |                       |
|------|-----------------------|
| Type | SMOKING QUESTIONNAIRE |
|------|-----------------------|

---

|                               |                           |
|-------------------------------|---------------------------|
| Was paper questionnaire used? | Yes <input type="radio"/> |
|-------------------------------|---------------------------|

---

|                 |       |
|-----------------|-------|
| Reason not done | <hr/> |
|-----------------|-------|

---

|                    |                            |
|--------------------|----------------------------|
| Date of assessment | 15 JAN 2014<br>DD/MMM/YYYY |
|--------------------|----------------------------|

---

|                    |                                 |
|--------------------|---------------------------------|
| Time of assessment | 20:52<br>hour:min 24-hour clock |
|--------------------|---------------------------------|

---

|  |   |
|--|---|
| 1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)? | Daily smoker (at least one cigarette per day, disregarding religious fasting) <input type="radio"/> |
|--|---|

---

|  |                           |
|--|---------------------------|
| 2. Have you ever smoked 100 cigarettes or more in your life? | Yes <input type="radio"/> |
|--|---------------------------|

---

|  |                           |
|--|---------------------------|
| 3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day? | Yes <input type="radio"/> |
|--|---------------------------|

---

|   |          |
|---|----------|
| 4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly? | 22 Years |
|---|----------|

---

5. If you are an ex-smoker of cigarettes: For how long have you quit now?

---

|       |       |
|-------|-------|
| Years | <hr/> |
|-------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:12**

**Generated On: 20 Jul 2016 11:47:42**

---

Months

---

---

Days

---

---

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?  
(Please add together any separate periods of quitting)

---

Years

---

Months

---

Days

---

---

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking?

---

Time

15 years ago ☒

---

8. On average, how many Manufactured cigarettes  
do/did you smoke per day?

---

Manufactured Cigarettes  
per day

10

---

8. On average, how many Hand-rolled Cigarettes do/did  
you smoke per day?

---

None ☒

Hand-rolled Cigarettes  
per day

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:12**

**Generated On: 20 Jul 2016 11:47:42**

---

8. On average, how many cigars do/did you smoke per  
day?

None ☐

---

Cigars  
per day

---

8. On average, how many pipes do/did you smoke per  
day?

None ☐

---

Pipes  
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:12**

**Generated On: 20 Jul 2016 11:47:42**

---

|      |                       |
|------|-----------------------|
| Type | SMOKING QUESTIONNAIRE |
|------|-----------------------|

---

|                               |                           |
|-------------------------------|---------------------------|
| Was paper questionnaire used? | Yes <input type="radio"/> |
|-------------------------------|---------------------------|

---

|                 |       |
|-----------------|-------|
| Reason not done | <hr/> |
|-----------------|-------|

---

|                    |                            |
|--------------------|----------------------------|
| Date of assessment | 15 JAN 2014<br>DD/MMM/YYYY |
|--------------------|----------------------------|

---

|                    |                                 |
|--------------------|---------------------------------|
| Time of assessment | 20:52<br>hour:min 24-hour clock |
|--------------------|---------------------------------|

---

|  |   |
|--|---|
| 1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)? | Daily smoker (at least one cigarette per day, disregarding religious fasting) <input type="radio"/> |
|--|---|

---

|  |                           |
|--|---------------------------|
| 2. Have you ever smoked 100 cigarettes or more in your life? | Yes <input type="radio"/> |
|--|---------------------------|

---

|  |                           |
|--|---------------------------|
| 3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day? | Yes <input type="radio"/> |
|--|---------------------------|

---

|   |          |
|---|----------|
| 4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly? | 22 Years |
|---|----------|

---

|   |  |
|---|--|
| 5. If you are an ex-smoker of cigarettes: For how long have you quit now? |  |
|---|--|

---

|       |       |
|-------|-------|
| Years | <hr/> |
|-------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:12**

**Generated On: 20 Jul 2016 11:47:42**

---

Months

---

---

Days

---

---

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?  
(Please add together any separate periods of quitting)

---

Years

---

Months

---

Days

---

---

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking?

---

Time

20 years ago ☒

---

8. On average, how many Manufactured cigarettes  
do/did you smoke per day?

---

Manufactured Cigarettes  
per day

10

---

8. On average, how many Hand-rolled Cigarettes do/did  
you smoke per day?

---

None ☒

Hand-rolled Cigarettes  
per day

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:12**

**Generated On: 20 Jul 2016 11:47:42**

---

8. On average, how many cigars do/did you smoke per  
day?

None ☐

---

Cigars  
per day

---

8. On average, how many pipes do/did you smoke per  
day?

None ☐

---

Pipes  
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (7)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:12**

**Generated On: 20 Jul 2016 11:47:42**

---

|      |                       |
|------|-----------------------|
| Type | SMOKING QUESTIONNAIRE |
|------|-----------------------|

---

|                               |                           |
|-------------------------------|---------------------------|
| Was paper questionnaire used? | Yes <input type="radio"/> |
|-------------------------------|---------------------------|

---

|                 |       |
|-----------------|-------|
| Reason not done | <hr/> |
|-----------------|-------|

---

|                    |                            |
|--------------------|----------------------------|
| Date of assessment | 15 JAN 2014<br>DD/MMM/YYYY |
|--------------------|----------------------------|

---

|                    |                                 |
|--------------------|---------------------------------|
| Time of assessment | 20:52<br>hour:min 24-hour clock |
|--------------------|---------------------------------|

---

|  |   |
|--|---|
| 1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)? | Daily smoker (at least one cigarette per day, disregarding religious fasting) <input type="radio"/> |
|--|---|

---

|  |                           |
|--|---------------------------|
| 2. Have you ever smoked 100 cigarettes or more in your life? | Yes <input type="radio"/> |
|--|---------------------------|

---

|  |                           |
|--|---------------------------|
| 3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day? | Yes <input type="radio"/> |
|--|---------------------------|

---

|   |          |
|---|----------|
| 4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly? | 22 Years |
|---|----------|

---

|   |  |
|---|--|
| 5. If you are an ex-smoker of cigarettes: For how long have you quit now? |  |
|---|--|

---

|       |       |
|-------|-------|
| Years | <hr/> |
|-------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (7)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:12**

**Generated On: 20 Jul 2016 11:47:42**

---

Months

---

---

Days

---

---

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?  
(Please add together any separate periods of quitting)

---

Years

---

Months

---

Days

---

---

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking?

---

Time

More than 20 years ago ☒

---

---

8. On average, how many Manufactured cigarettes do/did you smoke per day?

---

Manufactured Cigarettes  
per day

08

---

---

8. On average, how many Hand-rolled Cigarettes do/did you smoke per day?

---

None ☒

---

Hand-rolled Cigarettes  
per day

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (7)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:12**

**Generated On: 20 Jul 2016 11:47:42**

---

8. On average, how many cigars do/did you smoke per  
day?

None ☐

---

Cigars  
per day

---

8. On average, how many pipes do/did you smoke per  
day?

None ☐

---

Pipes  
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Supplemental Questions**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:14**

**Generated On: 20 Jul 2016 11:47:42**

---

Was paper questionnaire used? Yes ☒

---

Reason not done \_\_\_\_\_

---

Date of Assessment 15 JAN 2014  
DD/MMM/YYYY

---

Time of assessment 20:54

---

1. How long it takes for the subject to complete the SQ 03 minutes

---

Comments (open-end) \_\_\_\_\_

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Supplemental Questions (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:14**

**Generated On: 20 Jul 2016 11:47:42**

---

Was paper questionnaire used? Yes ☐

---

Reason not done \_\_\_\_\_

---

Date of Assessment 15 JAN 2014  
DD/MMM/YYYY

---

Time of assessment 20:54

---

1. How long it takes for the subject to complete the SQ 03 minutes

---

Question 2. Did the SQ capture your smoking behavior completely? ☐

---

Answer Yes ☐

---

Comments (open-end) \_\_\_\_\_

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Supplemental Questions (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:14**

**Generated On: 20 Jul 2016 11:47:42**

---

Was paper questionnaire used? Yes ☐

---

Reason not done \_\_\_\_\_

---

Date of Assessment 15 JAN 2014  
DD/MMM/YYYY

---

Time of assessment 20:54

---

1. How long it takes for the subject to complete the SQ 03 minutes

---

Question 3. Did the SQ capture your smoking behavior correctly? ☐

---

Answer Yes ☐

---

Comments (open-end) \_\_\_\_\_

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Supplemental Questions (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:14**

**Generated On: 20 Jul 2016 11:47:42**

---

Was paper questionnaire used? Yes ☐

---

Reason not done \_\_\_\_\_

---

Date of Assessment 15 JAN 2014  
DD/MMM/YYYY

---

Time of assessment 20:54

---

1. How long it takes for the subject to complete the SQ 03 minutes

---

Question 4. Did the SQ capture your smoking history completely? ☐

---

Answer Yes ☐

---

Comments (open-end) \_\_\_\_\_

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Supplemental Questions (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:14**

**Generated On: 20 Jul 2016 11:47:42**

---

Was paper questionnaire used? Yes ☐

---

Reason not done \_\_\_\_\_

---

Date of Assessment 15 JAN 2014  
DD/MMM/YYYY

---

Time of assessment 20:54

---

1. How long it takes for the subject to complete the SQ 03 minutes

---

Question 5. Did the SQ capture your smoking history correctly? ☐

---

Answer Yes ☐

---

Comments (open-end) \_\_\_\_\_

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Supplemental Questions (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:14**

**Generated On: 20 Jul 2016 11:47:42**

---

Was paper questionnaire used? Yes ☐

---

Reason not done \_\_\_\_\_

---

Date of Assessment 15 JAN 2014  
DD/MMM/YYYY

---

Time of assessment 20:54

---

1. How long it takes for the subject to complete the SQ 03 minutes

---

Question 6. Was the SQ ☐  
self-explaining?

---

Answer Yes ☐

---

Comments (open-end) \_\_\_\_\_

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Supplemental Questions (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:14**

**Generated On: 20 Jul 2016 11:47:42**

---

Was paper questionnaire used? Yes ☐

---

Reason not done \_\_\_\_\_

---

Date of Assessment 15 JAN 2014  
DD/MMM/YYYY

---

Time of assessment 20:54

---

1. How long it takes for the subject to complete the SQ 03 minutes

---

Question 7. Was the SQ easy to use? ☐

---

Answer Yes ☐

---

Comments (open-end) \_\_\_\_\_



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Questionnaire on smoking urges (QSU)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:15**

**Generated On: 20 Jul 2016 11:47:42**

---

|      |     |
|------|-----|
| Type | QSU |
|------|-----|

---

|               |         |
|---------------|---------|
| Date of Birth | (b) (6) |
|---------------|---------|

---

|                    |             |
|--------------------|-------------|
| Date of assessment | 2014 JAN 15 |
|--------------------|-------------|

DD/MMM/YYYY

---

|                    |       |
|--------------------|-------|
| Time of assessment | 20:39 |
|--------------------|-------|

hour:min 24-hour clock

---

|                   |  |
|-------------------|--|
| Assessment Status | Completed <input checked="" type="radio"/> |
|-------------------|--|

---

|  |   |
|--|---|
| 1. I have a desire for a cigarette right now | Do not agree or disagree <input checked="" type="radio"/> |
|--|---|

---

|   |   |
|---|---|
| 2. Nothing would be better than smoking a cigarette right now | Do not agree or disagree <input checked="" type="radio"/> |
|---|---|

---

|   |   |
|---|---|
| 3. If it were possible I would probably smoke now | Somewhat agree <input checked="" type="radio"/> |
|---|---|

---

|   |   |
|---|---|
| 4. I could control things better right now if I could smoke | Disagree <input checked="" type="radio"/> |
|---|---|

---

|  |   |
|--|---|
| 5. All I want right now is a cigarette | Somewhat agree <input checked="" type="radio"/> |
|--|---|

---

|                                   |  |
|-----------------------------------|--|
| 6. I have an urge for a cigarette | Agree <input checked="" type="radio"/> |
|-----------------------------------|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Questionnaire on smoking urges (QSU)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:15**

**Generated On: 20 Jul 2016 11:47:42**

---

7. A cigarette would taste good now Agree ☐

---

8. I would do almost anything for a cigarette now Somewhat disagree ☐

---

9. Smoking would make me less depressed Strongly disagree ☐

---

10. I am going to smoke as soon as possible Agree ☐

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:15**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:15**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112450000089        |
| Analyte                   | HPMA                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | -1                    |
| Celerion Study Number     | AA99128-03            |
| Date of Collection        | 2014-JAN-15           |
| Timepoint-minutes         |                       |
| Urine Start Day           |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:15**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

-1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:15**

**Generated On: 20 Jul 2016 11:47:42**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05112450000089 |
|----------------|----------------|

---

|         |      |
|---------|------|
| Analyte | CEMA |
|---------|------|

---

|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |       |
|------------|-------|
| Lab Status | OTHER |
|------------|-------|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | ANALYSIS NOT REQUIRED |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |    |
|--------------|----|
| Day of Visit | -1 |
|--------------|----|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-03 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-JAN-15 |
|--------------------|-------------|

---

|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

---

|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:15**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

-1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (CEMA, HPMa, HBMA) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:15**

**Generated On: 20 Jul 2016 11:47:42**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05112450000089 |
|----------------|----------------|

---

|         |      |
|---------|------|
| Analyte | HBMA |
|---------|------|

---

|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |       |
|------------|-------|
| Lab Status | OTHER |
|------------|-------|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | ANALYSIS NOT REQUIRED |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |    |
|--------------|----|
| Day of Visit | -1 |
|--------------|----|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-03 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-JAN-15 |
|--------------------|-------------|

---

|                   |       |
|-------------------|-------|
| Timepoint-minutes | _____ |
|-------------------|-------|

---

|                 |       |
|-----------------|-------|
| Urine Start Day | _____ |
|-----------------|-------|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:15**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

-1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (NNN, NNAL)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:15**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (NNN, NNAL) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:15**

**Generated On: 20 Jul 2016 11:47:42**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05112460000089 |
|----------------|----------------|

---

|         |      |
|---------|------|
| Analyte | NNAL |
|---------|------|

---

|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | PG/ML |
|-------------|-------|

---

|            |       |
|------------|-------|
| Lab Status | OTHER |
|------------|-------|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | ANALYSIS NOT REQUIRED |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |    |
|--------------|----|
| Day of Visit | -1 |
|--------------|----|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-04 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-JAN-15 |
|--------------------|-------------|

---

|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

---

|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (NNN, NNAL) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:15**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

-1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (NNN, NNAL) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:15**

**Generated On: 20 Jul 2016 11:47:42**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05112460000089 |
|----------------|----------------|

---

|         |     |
|---------|-----|
| Analyte | NNN |
|---------|-----|

---

|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | PG/ML |
|-------------|-------|

---

|            |       |
|------------|-------|
| Lab Status | OTHER |
|------------|-------|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | ANALYSIS NOT REQUIRED |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |    |
|--------------|----|
| Day of Visit | -1 |
|--------------|----|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-04 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-JAN-15 |
|--------------------|-------------|

---

|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

---

|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (NNN, NNAL) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:15**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

-1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (HEMA)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:15**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (HEMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:15**

**Generated On: 20 Jul 2016 11:47:42**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05112470000089 |
|----------------|----------------|

---

|         |      |
|---------|------|
| Analyte | HEMA |
|---------|------|

---

|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |       |
|------------|-------|
| Lab Status | OTHER |
|------------|-------|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | ANALYSIS NOT REQUIRED |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |    |
|--------------|----|
| Day of Visit | -1 |
|--------------|----|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-05 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-JAN-15 |
|--------------------|-------------|

---

|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

---

|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (HEMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:15**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

-1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:15**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:15**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112480000056        |
| Analyte                   | COT                   |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | -1                    |
| Celerion Study Number     | AA99128-06            |
| Date of Collection        | 2014-JAN-15           |
| Timepoint-minutes         |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:15**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine Start Day

---

Urine End Day

-1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:15**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112480000056        |
| Analyte                   | COT-GLUC              |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | -1                    |
| Celerion Study Number     | AA99128-06            |
| Date of Collection        | 2014-JAN-15           |
| Timepoint-minutes         |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:15**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine Start Day

---

Urine End Day

-1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:15**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112480000056        |
| Analyte                   | NIC                   |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | -1                    |
| Celerion Study Number     | AA99128-06            |
| Date of Collection        | 2014-JAN-15           |
| Timepoint-minutes         |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:15**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine Start Day

---

Urine End Day

-1

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:15**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112480000056        |
| Analyte                   | NIC-GLUC              |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | -1                    |
| Celerion Study Number     | AA99128-06            |
| Date of Collection        | 2014-JAN-15           |
| Timepoint-minutes         |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:15**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine Start Day

---

Urine End Day

-1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:15**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112480000056        |
| Analyte                   | THCOT                 |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | -1                    |
| Celerion Study Number     | AA99128-06            |
| Date of Collection        | 2014-JAN-15           |
| Timepoint-minutes         |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:15**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine Start Day

---

Urine End Day

-1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:15**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112480000056        |
| Analyte                   | THCOT-GLUC            |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | -1                    |
| Celerion Study Number     | AA99128-06            |
| Date of Collection        | 2014-JAN-15           |
| Timepoint-minutes         |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:15**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine Start Day

---

Urine End Day

-1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (3-OH BaP)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:16**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (3-OH BaP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:16**

**Generated On: 20 Jul 2016 11:47:42**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05112490000089 |
|----------------|----------------|

---

|         |          |
|---------|----------|
| Analyte | 3-OH BAP |
|---------|----------|

---

|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | FG/ML |
|-------------|-------|

---

|            |       |
|------------|-------|
| Lab Status | OTHER |
|------------|-------|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | ANALYSIS NOT REQUIRED |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |    |
|--------------|----|
| Day of Visit | -1 |
|--------------|----|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-07 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-JAN-15 |
|--------------------|-------------|

---

|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

---

|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (3-OH BaP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:16**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

-1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:16**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:16**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112510000089        |
| Analyte                   | 1-NA                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | PG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | -1                    |
| Celerion Study Number     | AA99128-09            |
| Date of Collection        | 2014-JAN-15           |
| Timepoint-minutes         |                       |
| Urine Start Day           |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:16**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

-1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:16**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112510000089        |
| Analyte                   | 2-NA                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | PG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | -1                    |
| Celerion Study Number     | AA99128-09            |
| Date of Collection        | 2014-JAN-15           |
| Timepoint-minutes         |                       |
| Urine Start Day           |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:16**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

-1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:16**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112510000089        |
| Analyte                   | 4-ABP                 |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | PG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | -1                    |
| Celerion Study Number     | AA99128-09            |
| Date of Collection        | 2014-JAN-15           |
| Timepoint-minutes         |                       |
| Urine Start Day           |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:16**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

-1

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:16**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112510000089        |
| Analyte                   | O-TOL                 |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | PG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | -1                    |
| Celerion Study Number     | AA99128-09            |
| Date of Collection        | 2014-JAN-15           |
| Timepoint-minutes         |                       |
| Urine Start Day           |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:16**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

-1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (11-dTXb2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:15**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (11-dTXb2) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:15**

**Generated On: 20 Jul 2016 11:47:42**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05112530000057 |
|----------------|----------------|

---

|         |          |
|---------|----------|
| Analyte | 11-DTXB2 |
|---------|----------|

---

|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | PG/ML |
|-------------|-------|

---

|            |       |
|------------|-------|
| Lab Status | OTHER |
|------------|-------|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | ANALYSIS NOT REQUIRED |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |    |
|--------------|----|
| Day of Visit | -1 |
|--------------|----|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-11 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-JAN-15 |
|--------------------|-------------|

---

|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

---

|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (11-dTXb2) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:15**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

-1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (iPF2a-III)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:15**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (iPF2a-III) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:15**

**Generated On: 20 Jul 2016 11:47:42**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05112540000057 |
|----------------|----------------|

---

|         |           |
|---------|-----------|
| Analyte | IPF2A-III |
|---------|-----------|

---

|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | PG/ML |
|-------------|-------|

---

|            |       |
|------------|-------|
| Lab Status | OTHER |
|------------|-------|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | ANALYSIS NOT REQUIRED |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |    |
|--------------|----|
| Day of Visit | -1 |
|--------------|----|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-12 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-JAN-15 |
|--------------------|-------------|

---

|                   |       |
|-------------------|-------|
| Timepoint-minutes | _____ |
|-------------------|-------|

---

|                 |       |
|-----------------|-------|
| Urine Start Day | _____ |
|-----------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (iPF2a-III) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:15**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

-1

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (1-OHP)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:16**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (1-OHP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:16**

**Generated On: 20 Jul 2016 11:47:42**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05115190001178 |
|----------------|----------------|

---

|         |       |
|---------|-------|
| Analyte | 1-OHP |
|---------|-------|

---

|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | PG/ML |
|-------------|-------|

---

|            |       |
|------------|-------|
| Lab Status | OTHER |
|------------|-------|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | ANALYSIS NOT REQUIRED |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |    |
|--------------|----|
| Day of Visit | -1 |
|--------------|----|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99598-03 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-JAN-15 |
|--------------------|-------------|

---

|                   |       |
|-------------------|-------|
| Timepoint-minutes | _____ |
|-------------------|-------|

---

|                 |       |
|-----------------|-------|
| Urine Start Day | _____ |
|-----------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (1-OHP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:16**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

-1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (SPMA, SBMA)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:15**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (SPMA, SBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:15**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05115170000089        |
| Analyte                   | SBMA                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | -1                    |
| Celerion Study Number     | AA99598-01            |
| Date of Collection        | 2014-JAN-15           |
| Timepoint-minutes         |                       |
| Urine Start Day           |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (SPMA, SBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:15**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

-1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (SPMA, SBMA) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:15**

**Generated On: 20 Jul 2016 11:47:42**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05115170000089 |
|----------------|----------------|

---

|         |      |
|---------|------|
| Analyte | SPMA |
|---------|------|

---

|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |       |
|------------|-------|
| Lab Status | OTHER |
|------------|-------|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | ANALYSIS NOT REQUIRED |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |    |
|--------------|----|
| Day of Visit | -1 |
|--------------|----|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99598-01 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-JAN-15 |
|--------------------|-------------|

---

|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

---

|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (SPMA, SBMA) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:15**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

-1

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (MHBMA)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:15**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (MHBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:15**

**Generated On: 20 Jul 2016 11:47:42**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05115180000089 |
|----------------|----------------|

---

|         |       |
|---------|-------|
| Analyte | MHBMA |
|---------|-------|

---

|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |       |
|------------|-------|
| Lab Status | OTHER |
|------------|-------|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | ANALYSIS NOT REQUIRED |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |  |
|--------------|--|
| Day of Visit |  |
|--------------|--|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99598-02 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-JAN-15 |
|--------------------|-------------|

---

|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

---

|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (MHBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:15**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

-1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (Creatinine)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:16**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (Creatinine) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:16**

**Generated On: 20 Jul 2016 11:47:42**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05115160000089 |
|----------------|----------------|

---

|         |            |
|---------|------------|
| Analyte | CREATININE |
|---------|------------|

---

|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | MG/DL |
|-------------|-------|

---

|            |       |
|------------|-------|
| Lab Status | OTHER |
|------------|-------|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | ANALYSIS NOT REQUIRED |
|----------------|-----------------------|

---

|                  |                    |
|------------------|--------------------|
| Detection method | SPECTROPHOTOMETRIC |
|------------------|--------------------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |    |
|--------------|----|
| Day of Visit | -1 |
|--------------|----|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-14 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-JAN-15 |
|--------------------|-------------|

---

|                   |       |
|-------------------|-------|
| Timepoint-minutes | _____ |
|-------------------|-------|

---

|                 |       |
|-----------------|-------|
| Urine Start Day | _____ |
|-----------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (Creatinine) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:16**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

-1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Date of Visit**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:17**

**Generated On: 20 Jul 2016 11:47:42**

---

Date of Visit

16 JAN 2014  
DD/MMM/YYYY

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Randomization**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:17**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                 |      |
|---------------------------------|------|
| Randomization number (4 digits) | 3005 |
|---------------------------------|------|

---

|                |  |
|----------------|--|
| Allocation Arm | THS 2.2 menthol <input checked="" type="radio"/> |
|----------------|--|

---

|                       |  |
|-----------------------|--|
| Cigarette Consumption | 10 – 19 conventional<br>menthol cigarettesper day <input checked="" type="radio"/> |
|-----------------------|--|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Vital Signs**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:17**

**Generated On: 20 Jul 2016 11:47:42**

---

Were Vitals Signs assessed? Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

Has the subject smoked within 15 minutes prior to assessment No ☒

---

Time of assessment 10:28  
hour:min 24-hour clock

---

Pulse rate 72  
beats per minute

---

Respiratory rate 18  
breaths per minute

---

Blood Pressure (systolic) 125  
mmHg

---

Blood Pressure (diastolic) 84  
mmHg

---

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Haematology**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:16**

**Generated On: 20 Jul 2016 11:47:42**

---

Were samples collected?

Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

Was the subject fasting for at least 10 hours at time of  
sample collection?

Yes ☒

---

Please document clinically relevant abnormalities in the AE form

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Clinical Chemistry**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:16**

**Generated On: 20 Jul 2016 11:47:42**

---

Were samples collected?

Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

Was the subject fasting for at least 10 hours at time of  
sample collection?

Yes ☒

---

Please document clinically relevant abnormalities in the AE form

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Urine analysis**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:16**

**Generated On: 20 Jul 2016 11:47:42**

---

Were samples collected?

Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Plasma Nicotine Sample**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:17**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 16 JAN 2014 |
|---------------------|-------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 20:46 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Plasma Cotinine Sample**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:17**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 16 JAN 2014 |
|---------------------|-------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 20:46 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: CoHb Blood Sample <D0> (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:16**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 16 JAN 2014 |
|---------------------|-------------|

---

|           |  |
|-----------|--|
| Timepoint | Prior to gas transfer<br>assessment and prior to<br>product use <input checked="" type="radio"/> |
|-----------|--|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 06:42 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: CoHb Blood Sample <D0> (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:16**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 16 JAN 2014 |
|---------------------|-------------|

---

|           |  |
|-----------|--|
| Timepoint | 20:00 - 21:30 <input checked="" type="radio"/> |
|-----------|--|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 20:46 |
|--------------------------------|-------|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Oxysterols**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:17**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|  |                                      |
|--|--------------------------------------|
| Was the subject fasting for at least 10 hours at time of<br>sample collection? | Yes <input checked="" type="radio"/> |
|--|--------------------------------------|

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 16 JAN 2014 |
|---------------------|-------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 06:42 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: CO Breath Test (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:16**

**Generated On: 20 Jul 2016 11:47:42**

---

|                     |       |
|---------------------|-------|
| Assessment not done | False |
|---------------------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                |   |
|----------------|---|
| Scheduled Time | Within 15 min prior to smoking <input checked="" type="radio"/> |
|----------------|---|

---

|   |       |
|---|-------|
| Actual Time of Assessment<br>hour:min 24-hour clock | 09:15 |
|---|-------|

---

|             |    |
|-------------|----|
| Result(ppm) | 17 |
|-------------|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: CO Breath Test (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:16**

**Generated On: 20 Jul 2016 11:47:42**

---

|                     |       |
|---------------------|-------|
| Assessment not done | False |
|---------------------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                |   |
|----------------|---|
| Scheduled Time | 12:00 - 13:30  |
|----------------|---|

---

|   |       |
|---|-------|
| Actual Time of Assessment<br>hour:min 24-hour clock | 12:16 |
|---|-------|

---

|             |    |
|-------------|----|
| Result(ppm) | 25 |
|-------------|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: CO Breath Test (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:16**

**Generated On: 20 Jul 2016 11:47:42**

---

|                     |       |
|---------------------|-------|
| Assessment not done | False |
|---------------------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                |  |
|----------------|--|
| Scheduled Time | 16:00 - 17:30 <input checked="" type="radio"/> |
|----------------|--|

---

|   |       |
|---|-------|
| Actual Time of Assessment<br>hour:min 24-hour clock | 16:21 |
|---|-------|

---

|             |    |
|-------------|----|
| Result(ppm) | 43 |
|-------------|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: CO Breath Test (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:16**

**Generated On: 20 Jul 2016 11:47:42**

---

|                     |       |
|---------------------|-------|
| Assessment not done | False |
|---------------------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                |  |
|----------------|--|
| Scheduled Time | 20:00 - 21:30 <input checked="" type="radio"/> |
|----------------|--|

---

|   |       |
|---|-------|
| Actual Time of Assessment<br>hour:min 24-hour clock | 20:36 |
|---|-------|

---

|             |    |
|-------------|----|
| Result(ppm) | 29 |
|-------------|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: CYP2A6 activity Sample**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:17**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

Date of sample collection  
DD/MMM/YYYY

Time of sample collection  
hour:min 24-hour clock

Parameter

---

16 JAN 2014

06:42

trans-3'-hydroxyc  
otinine

---

16 JAN 2014

06:42

cotinine

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: CYP1A2 activity Sample**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:17**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                |                        |
|--------------------------------|------------------------|
| Time of caffeine tablet intake | 10:16                  |
|                                | hour:min 24-hour clock |

---

|                            |       |
|----------------------------|-------|
| Sample collection Not Done | False |
|----------------------------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

| Date of sample collection<br>DD/MMM/YYYY | Time of sample collection<br>hour:min 24-hour clock | Parameter    |
|--|---|--------------|
| 16 JAN 2014                              | 16:16   | Caffeine     |
| 16 JAN 2014                              | 16:16   | Paraxanthine |

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Risk Marker: hs-CRP, fibrinogen, homocysteine, LDL, HDL,  
sICAM-1, HbA1c, Apo A1, Apo B**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:17**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 16 JAN 2014 |
|---------------------|-------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 06:42 |
|--------------------------------|-------|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: 24 hour urine collections**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:17**

**Generated On: 20 Jul 2016 11:47:42**

---

|            |                            |
|------------|----------------------------|
| Start Date | 16 JAN 2014<br>DD/MMM/YYYY |
|------------|----------------------------|

---

|            |                                 |
|------------|---------------------------------|
| Start Time | 05:57<br>hour:min 24-hour clock |
|------------|---------------------------------|

---

|          |                            |
|----------|----------------------------|
| End Date | 17 JAN 2014<br>DD/MMM/YYYY |
|----------|----------------------------|

---

|          |                                 |
|----------|---------------------------------|
| End Time | 06:10<br>hour:min 24-hour clock |
|----------|---------------------------------|

---

|        |            |
|--------|------------|
| Volume | 1860<br>mL |
|--------|------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Sample Urine Collection**

**Generated On: 20 Jul 2016 11:47:42**

---

Were samples for 24h collected?

Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

How many primary tubes were collected?

11

---

How many back up tubes were collected?

15

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:17**

**Generated On: 20 Jul 2016 11:47:42**

---

Date of Birth

(b) (6)

---

Date of assessment  
DD/MMM/YYYY

2014 JAN 16  
DD/MMM/YYYY

---

Time of assessment

06:30  
hour:min 24-hour clock

---

Assessment Status

Completed ☒

---

Please indicate for each of the items below, how you have been feeling over the past 24 hours

---

How have you been feeling over the past 24 hours?

None ☐

1. Angry, irritable, frustrated

---

How have you been feeling over the past 24 hours?

None ☐

2. Anxious, nervous

---

How have you been feeling over the past 24 hours?

None ☐

3. Depressed Mood, sad

---

How have you been feeling over the past 24 hours?

Moderate ☐

4. Desire or craving to smoke

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:17**

**Generated On: 20 Jul 2016 11:47:42**

---

How have you been feeling over the past 24 hours? Slight ☐

5. Difficulty concentrating

---

How have you been feeling over the past 24 hours? Moderate ☐

6. Increased appetite, hungry, weight gain

---

How have you been feeling over the past 24 hours? Slight ☐

7. Insomnia, sleep problems, awakening at night

---

How have you been feeling over the past 24 hours? Slight ☐

8. Restless

---

How have you been feeling over the past 24 hours? None ☐

9. Impatient

---

How have you been feeling over the past 24 hours? Slight ☐

10. Constipation

---

How have you been feeling over the past 24 hours? Slight ☐

11. Dizziness

---

How have you been feeling over the past 24 hours? None ☐

12. Coughing

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:17**

**Generated On: 20 Jul 2016 11:47:42**

---

How have you been feeling over the past 24 hours?

None ☐

13. Dreaming or nightmares

---

How have you been feeling over the past 24 hours?

None ☐

14. Nausea

---

How have you been feeling over the past 24 hours?

None ☐

15. Sore Throat

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Cough Assessment**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

Date of Birth

(b) (6)

---

Date of assessment  
DD/MMM/YYYY

2014 JAN 16  
DD/MMM/YYYY

---

Time of assessment

06:28  
hour:min 24-hour clock

---

Assessment Status

Completed ☒

---

Have you experienced a regular need to cough e.g.  
coughing several times in the last 24 hrs?

No ☒

---

If YES, please answer the following questions:

---

First Question: Cough Impact Scale  
How much is your cough bothering you?

-9

---

Second Question: Cough Intensity Scale:  
How intense is your cough?

Not Applicable ☒

---

Third Question: Cough Frequency Scale:  
How frequently do you normally have to cough each  
day?

Not Applicable ☒

---

Fourth Question: Sputum Production  
To what extent do you produce sputum when coughing?

Not Applicable ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☐

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6)

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225570

---

Actual Collection Date 2014 01 16

---

Actual Collection Time 06:42

---

Specimen Condition \_\_\_\_\_

---

Battery ID RC1029

---

Battery Name TRIGLYCERIDES

---

Lab Test ID RCT19

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

|                                   |  |
|-----------------------------------|--|
| Lab Test Name                     | TRIGLYCERIDES (GPO)                      |
| Test ID                           |  |
| Test Status                       | Done <input checked="" type="checkbox"/> |
| Reported Text Result              | 75                                       |
| Reported Numeric Result           | 75                                       |
| Reference Range low               | 45                                       |
| Reference Range high              | 214                                      |
| Range Units                       | MG/DL                                    |
| Conventional Text Result          |  |
| Conventional Numeric Result       |  |
| Conventional Reference Range Low  |  |
| Conventional Reference Range High |  |
| Conventional Units                |  |
| SI Text Result                    |  |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☒

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6)

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☒

---

Accession ID V225570

---

Actual Collection Date 2014 01 16

---

Actual Collection Time 06:42

---

Specimen Condition \_\_\_\_\_

---

Battery ID RC1092

---

Battery Name FASTING GLUCOSE

---

Lab Test ID RCT142

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | FASTING GLUCOSE                       |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 90                                    |
| Reported Numeric Result           | 90                                    |
| Reference Range low               | 70                                    |
| Reference Range high              | 100                                   |
| Range Units                       | MG/DL                                 |
| Conventional Text Result          |                                       |
| Conventional Numeric Result       |                                       |
| Conventional Reference Range Low  |                                       |
| Conventional Reference Range High |                                       |
| Conventional Units                |                                       |
| SI Text Result                    |                                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☒

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6) 

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☒

---

Accession ID V225570

---

Actual Collection Date 2014 01 16

---

Actual Collection Time 06:42

---

Specimen Condition \_\_\_\_\_

---

Battery ID RC272

---

Battery Name TOTAL CHOLESTEROL

---

Lab Test ID RCT20

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

Lab Test Name


CHOLESTEROL (HIGH  
PERFORMANCE)

---

Test ID

---

Test Status

Done 

---

Reported Text Result

171

---

Reported Numeric Result

171

---

Reference Range low

155

---

Reference Range high

265

---

Range Units

MG/DL

---

Conventional Text Result

---

Conventional Numeric Result

---

Conventional Reference Range Low

---

Conventional Reference Range High

---

Conventional Units

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Text Result

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☒

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6) 

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☒

---

Accession ID V225570

---

Actual Collection Date 2014 01 16

---

Actual Collection Time 06:42

---

Specimen Condition \_\_\_\_\_

---

Battery ID RC9255

---

Battery Name CHEMISTRY PANEL

---

Lab Test ID RCT1

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

|                                   |                               |
|-----------------------------------|-------------------------------|
| Lab Test Name                     | TOTAL BILIRUBIN               |
| Test ID                           |                               |
| Test Status                       | Done <input type="checkbox"/> |
| Reported Text Result              | 0.3                           |
| Reported Numeric Result           | 0.3                           |
| Reference Range low               | 0.2                           |
| Reference Range high              | 1.2                           |
| Range Units                       | MG/DL                         |
| Conventional Text Result          |                               |
| Conventional Numeric Result       |                               |
| Conventional Reference Range Low  |                               |
| Conventional Reference Range High |                               |
| Conventional Units                |                               |
| SI Text Result                    |                               |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☐

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6)

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225570

---

Actual Collection Date 2014 01 16

---

Actual Collection Time 06:42

---

Specimen Condition \_\_\_\_\_

---

Battery ID RC9255

---

Battery Name CHEMISTRY PANEL

---

Lab Test ID RCT12

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | TOTAL PROTEIN                         |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 7.1                                   |
| Reported Numeric Result           | 7.1                                   |
| Reference Range low               | 6.1                                   |
| Reference Range high              | 8.4                                   |
| Range Units                       | G/DL                                  |
| Conventional Text Result          |                                       |
| Conventional Numeric Result       |                                       |
| Conventional Reference Range Low  |                                       |
| Conventional Reference Range High |                                       |
| Conventional Units                |                                       |
| SI Text Result                    |                                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☐

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6)

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225570

---

Actual Collection Date 2014 01 16

---

Actual Collection Time 06:42

---

Specimen Condition \_\_\_\_\_

---

Battery ID RC9255

---

Battery Name CHEMISTRY PANEL

---

Lab Test ID RCT13

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | ALBUMIN                               |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 3.7                                   |
| Reported Numeric Result           | 3.7                                   |
| Reference Range low               | 3.3                                   |
| Reference Range high              | 4.9                                   |
| Range Units                       | G/DL                                  |
| Conventional Text Result          |                                       |
| Conventional Numeric Result       |                                       |
| Conventional Reference Range Low  |                                       |
| Conventional Reference Range High |                                       |
| Conventional Units                |                                       |
| SI Text Result                    |                                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (7)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☐

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6)

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225570

---

Actual Collection Date 2014 01 16

---

Actual Collection Time 06:42

---

Specimen Condition \_\_\_\_\_

---

Battery ID RC9255

---

Battery Name CHEMISTRY PANEL

---

Lab Test ID RCT1407

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (7)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

|                                   |                            |
|-----------------------------------|----------------------------|
| Lab Test Name                     | ALKALINE PHOSPHATASE       |
| Test ID                           |                            |
| Test Status                       | Done <input type="radio"/> |
| Reported Text Result              | 45                         |
| Reported Numeric Result           | 45                         |
| Reference Range low               | 31                         |
| Reference Range high              | 106                        |
| Range Units                       | U/L                        |
| Conventional Text Result          |                            |
| Conventional Numeric Result       |                            |
| Conventional Reference Range Low  |                            |
| Conventional Reference Range High |                            |
| Conventional Units                |                            |
| SI Text Result                    |                            |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (7)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (8)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☐

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6)

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225570

---

Actual Collection Date 2014 01 16

---

Actual Collection Time 06:42

---

Specimen Condition \_\_\_\_\_

---

Battery ID RC9255

---

Battery Name CHEMISTRY PANEL

---

Lab Test ID RCT1408

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (8)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

|                                   |                               |
|-----------------------------------|-------------------------------|
| Lab Test Name                     | LDH                           |
| Test ID                           |                               |
| Test Status                       | Done <input type="checkbox"/> |
| Reported Text Result              | 142                           |
| Reported Numeric Result           | 142                           |
| Reference Range low               | 53                            |
| Reference Range high              | 234                           |
| Range Units                       | U/L                           |
| Conventional Text Result          |                               |
| Conventional Numeric Result       |                               |
| Conventional Reference Range Low  |                               |
| Conventional Reference Range High |                               |
| Conventional Units                |                               |
| SI Text Result                    |                               |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (8)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (9)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☐

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6)

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225570

---

Actual Collection Date 2014 01 16

---

Actual Collection Time 06:42

---

Specimen Condition \_\_\_\_\_

---

Battery ID RC9255

---

Battery Name CHEMISTRY PANEL

---

Lab Test ID RCT15

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (9)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | SERUM SODIUM                          |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 140                                   |
| Reported Numeric Result           | 140                                   |
| Reference Range low               | 132                                   |
| Reference Range high              | 147                                   |
| Range Units                       | MEQ/L                                 |
| Conventional Text Result          |                                       |
| Conventional Numeric Result       |                                       |
| Conventional Reference Range Low  |                                       |
| Conventional Reference Range High |                                       |
| Conventional Units                |                                       |
| SI Text Result                    |                                       |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (9)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (10)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

---

|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

---

|             |   |
|-------------|---|
| Subject Sex | F |
|-------------|---|

---

|                       |         |
|-----------------------|---------|
| Subject Date of Birth | (b) (6) |
|-----------------------|---------|

---

|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | V225570 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 01 16 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:42 |
|------------------------|-------|

---

|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

---

|            |        |
|------------|--------|
| Battery ID | RC9255 |
|------------|--------|

---

|              |                 |
|--------------|-----------------|
| Battery Name | CHEMISTRY PANEL |
|--------------|-----------------|

---

|             |       |
|-------------|-------|
| Lab Test ID | RCT16 |
|-------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (10)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

|                                   |  |
|-----------------------------------|--|
| Lab Test Name                     | SERUM POTASSIUM                          |
| Test ID                           |  |
| Test Status                       | Done <input checked="" type="checkbox"/> |
| Reported Text Result              | 4.0                                      |
| Reported Numeric Result           | 4.0                                      |
| Reference Range low               | 3.4                                      |
| Reference Range high              | 5.4                                      |
| Range Units                       | MEQ/L                                    |
| Conventional Text Result          |  |
| Conventional Numeric Result       |  |
| Conventional Reference Range Low  |  |
| Conventional Reference Range High |  |
| Conventional Units                |  |
| SI Text Result                    |  |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (10)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (11)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

---

|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

---

|             |   |
|-------------|---|
| Subject Sex | F |
|-------------|---|

---

|                       |         |
|-----------------------|---------|
| Subject Date of Birth | (b) (6) |
|-----------------------|---------|

---

|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | V225570 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 01 16 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:42 |
|------------------------|-------|

---

|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

---

|            |        |
|------------|--------|
| Battery ID | RC9255 |
|------------|--------|

---

|              |                 |
|--------------|-----------------|
| Battery Name | CHEMISTRY PANEL |
|--------------|-----------------|

---

|             |       |
|-------------|-------|
| Lab Test ID | RCT29 |
|-------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (11)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | DIRECT BILIRUBIN                      |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | <0.1                                  |
| Reported Numeric Result           |                                       |
| Reference Range low               | 0.0                                   |
| Reference Range high              | 0.4                                   |
| Range Units                       | MG/DL                                 |
| Conventional Text Result          |                                       |
| Conventional Numeric Result       |                                       |
| Conventional Reference Range Low  |                                       |
| Conventional Reference Range High |                                       |
| Conventional Units                |                                       |
| SI Text Result                    |                                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (11)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (12)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☐

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6)

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225570

---

Actual Collection Date 2014 01 16

---

Actual Collection Time 06:42

---

Specimen Condition \_\_\_\_\_

---

Battery ID RC9255

---

Battery Name CHEMISTRY PANEL

---

Lab Test ID RCT3

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (12)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

|                                   |                            |
|-----------------------------------|----------------------------|
| Lab Test Name                     | GGT                        |
| Test ID                           |                            |
| Test Status                       | Done <input type="radio"/> |
| Reported Text Result              | 19                         |
| Reported Numeric Result           | 19                         |
| Reference Range low               | 4                          |
| Reference Range high              | 49                         |
| Range Units                       | U/L                        |
| Conventional Text Result          |                            |
| Conventional Numeric Result       |                            |
| Conventional Reference Range Low  |                            |
| Conventional Reference Range High |                            |
| Conventional Units                |                            |
| SI Text Result                    |                            |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (12)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (13)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☐

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6)

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225570

---

Actual Collection Date 2014 01 16

---

Actual Collection Time 06:42

---

Specimen Condition \_\_\_\_\_

---

Battery ID RC9255

---

Battery Name CHEMISTRY PANEL

---

Lab Test ID RCT392

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (13)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

|               |                           |
|---------------|---------------------------|
| Lab Test Name | CREATININE (RATE BLANKED) |
|---------------|---------------------------|

---

|         |       |
|---------|-------|
| Test ID | <hr/> |
|---------|-------|

---

|             |                                       |
|-------------|---------------------------------------|
| Test Status | Done <input checked="" type="radio"/> |
|-------------|---------------------------------------|

---

|                      |     |
|----------------------|-----|
| Reported Text Result | 0.7 |
|----------------------|-----|

---

|                         |     |
|-------------------------|-----|
| Reported Numeric Result | 0.7 |
|-------------------------|-----|

---

|                     |     |
|---------------------|-----|
| Reference Range low | 0.4 |
|---------------------|-----|

---

|                      |     |
|----------------------|-----|
| Reference Range high | 1.1 |
|----------------------|-----|

---

|             |       |
|-------------|-------|
| Range Units | MG/DL |
|-------------|-------|

---

|                          |       |
|--------------------------|-------|
| Conventional Text Result | <hr/> |
|--------------------------|-------|

---

|                             |       |
|-----------------------------|-------|
| Conventional Numeric Result | <hr/> |
|-----------------------------|-------|

---

|                                  |       |
|----------------------------------|-------|
| Conventional Reference Range Low | <hr/> |
|----------------------------------|-------|

---

|                                   |       |
|-----------------------------------|-------|
| Conventional Reference Range High | <hr/> |
|-----------------------------------|-------|

---

|                    |       |
|--------------------|-------|
| Conventional Units | <hr/> |
|--------------------|-------|

---

|                |       |
|----------------|-------|
| SI Text Result | <hr/> |
|----------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (13)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (14)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☐

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6)

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225570

---

Actual Collection Date 2014 01 16

---

Actual Collection Time 06:42

---

Specimen Condition \_\_\_\_\_

---

Battery ID RC9255

---

Battery Name CHEMISTRY PANEL

---

Lab Test ID RCT4

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (14)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

|                                   |                            |
|-----------------------------------|----------------------------|
| Lab Test Name                     | ALT (SGPT)                 |
| Test ID                           |                            |
| Test Status                       | Done <input type="radio"/> |
| Reported Text Result              | 13                         |
| Reported Numeric Result           | 13                         |
| Reference Range low               | 6                          |
| Reference Range high              | 34                         |
| Range Units                       | U/L                        |
| Conventional Text Result          |                            |
| Conventional Numeric Result       |                            |
| Conventional Reference Range Low  |                            |
| Conventional Reference Range High |                            |
| Conventional Units                |                            |
| SI Text Result                    |                            |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (14)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (15)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

---

|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

---

|             |   |
|-------------|---|
| Subject Sex | F |
|-------------|---|

---

|                       |         |
|-----------------------|---------|
| Subject Date of Birth | (b) (6) |
|-----------------------|---------|

---

|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | V225570 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 01 16 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:42 |
|------------------------|-------|

---

|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

---

|            |        |
|------------|--------|
| Battery ID | RC9255 |
|------------|--------|

---

|              |                 |
|--------------|-----------------|
| Battery Name | CHEMISTRY PANEL |
|--------------|-----------------|

---

|             |      |
|-------------|------|
| Lab Test ID | RCT5 |
|-------------|------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (15)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

|                                   |                            |
|-----------------------------------|----------------------------|
| Lab Test Name                     | AST (SGOT)                 |
| Test ID                           |                            |
| Test Status                       | Done <input type="radio"/> |
| Reported Text Result              | 15                         |
| Reported Numeric Result           | 15                         |
| Reference Range low               | 9                          |
| Reference Range high              | 34                         |
| Range Units                       | U/L                        |
| Conventional Text Result          |                            |
| Conventional Numeric Result       |                            |
| Conventional Reference Range Low  |                            |
| Conventional Reference Range High |                            |
| Conventional Units                |                            |
| SI Text Result                    |                            |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (15)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (16)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☐

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6)

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225570

---

Actual Collection Date 2014 01 16

---

Actual Collection Time 06:42

---

Specimen Condition \_\_\_\_\_

---

Battery ID RC9255

---

Battery Name CHEMISTRY PANEL

---

Lab Test ID RCT6

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (16)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

|                                   |                            |
|-----------------------------------|----------------------------|
| Lab Test Name                     | UREA NITROGEN              |
| Test ID                           |                            |
| Test Status                       | Done <input type="radio"/> |
| Reported Text Result              | 11                         |
| Reported Numeric Result           | 11                         |
| Reference Range low               | 4                          |
| Reference Range high              | 24                         |
| Range Units                       | MG/DL                      |
| Conventional Text Result          |                            |
| Conventional Numeric Result       |                            |
| Conventional Reference Range Low  |                            |
| Conventional Reference Range High |                            |
| Conventional Units                |                            |
| SI Text Result                    |                            |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (16)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (17)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

---

|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

---

|             |   |
|-------------|---|
| Subject Sex | F |
|-------------|---|

---

|                       |         |
|-----------------------|---------|
| Subject Date of Birth | (b) (6) |
|-----------------------|---------|

---

|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | V225570 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 01 16 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:42 |
|------------------------|-------|

---

|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

---

|            |        |
|------------|--------|
| Battery ID | HM1604 |
|------------|--------|

---

|              |                                   |
|--------------|-----------------------------------|
| Battery Name | HEMATOLOGY<br>&DIFFERENTIAL PANEL |
|--------------|-----------------------------------|

---

|             |       |
|-------------|-------|
| Lab Test ID | HMT10 |
|-------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (17)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | MONOCYTES                             |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 0.32                                  |
| Reported Numeric Result           | 0.32                                  |
| Reference Range low               | 0.12                                  |
| Reference Range high              | 0.92                                  |
| Range Units                       | X10^3/UL                              |
| Conventional Text Result          |                                       |
| Conventional Numeric Result       |                                       |
| Conventional Reference Range Low  |                                       |
| Conventional Reference Range High |                                       |
| Conventional Units                |                                       |
| SI Text Result                    |                                       |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (17)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (18)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☒

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6) 

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☒

---

Accession ID V225570

---

Actual Collection Date 2014 01 16

---

Actual Collection Time 06:42

---

Specimen Condition \_\_\_\_\_

---

Battery ID HM1604

---

Battery Name HEMATOLOGY  
&DIFFERENTIAL PANEL

---

Lab Test ID HMT100

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (18)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

|                                   |                            |
|-----------------------------------|----------------------------|
| Lab Test Name                     | MCH                        |
| Test ID                           |                            |
| Test Status                       | Done <input type="radio"/> |
| Reported Text Result              | 30                         |
| Reported Numeric Result           | 30                         |
| Reference Range low               | 26                         |
| Reference Range high              | 34                         |
| Range Units                       | PG                         |
| Conventional Text Result          |                            |
| Conventional Numeric Result       |                            |
| Conventional Reference Range Low  |                            |
| Conventional Reference Range High |                            |
| Conventional Units                |                            |
| SI Text Result                    |                            |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (18)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (19)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☐

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6) 

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225570

---

Actual Collection Date 2014 01 16

---

Actual Collection Time 06:42

---

Specimen Condition \_\_\_\_\_

---

Battery ID HM1604

---

Battery Name HEMATOLOGY  
&DIFFERENTIAL PANEL

---

Lab Test ID HMT102

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (19)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | MCHC                                  |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 33                                    |
| Reported Numeric Result           | 33                                    |
| Reference Range low               | 31                                    |
| Reference Range high              | 38                                    |
| Range Units                       | G/DL                                  |
| Conventional Text Result          |                                       |
| Conventional Numeric Result       |                                       |
| Conventional Reference Range Low  |                                       |
| Conventional Reference Range High |                                       |
| Conventional Units                |                                       |
| SI Text Result                    |                                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (19)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (20)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☒

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6) 

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☒

---

Accession ID V225570

---

Actual Collection Date 2014 01 16

---

Actual Collection Time 06:42

---

Specimen Condition \_\_\_\_\_

---

Battery ID HM1604

---

Battery Name HEMATOLOGY  
&DIFFERENTIAL PANEL

---

Lab Test ID HMT11

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (20)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | EOSINOPHILS                           |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 0.28                                  |
| Reported Numeric Result           | 0.28                                  |
| Reference Range low               | 0.00                                  |
| Reference Range high              | 0.57                                  |
| Range Units                       | X10^3/UL                              |
| Conventional Text Result          |                                       |
| Conventional Numeric Result       |                                       |
| Conventional Reference Range Low  |                                       |
| Conventional Reference Range High |                                       |
| Conventional Units                |                                       |
| SI Text Result                    |                                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (20)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (21)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☒

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6)

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☒

---

Accession ID V225570

---

Actual Collection Date 2014 01 16

---

Actual Collection Time 06:42

---

Specimen Condition \_\_\_\_\_

---

Battery ID HM1604

---

Battery Name HEMATOLOGY  
&DIFFERENTIAL PANEL

---

Lab Test ID HMT12

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (21)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

|                                   |                               |
|-----------------------------------|-------------------------------|
| Lab Test Name                     | BASOPHILS                     |
| Test ID                           |                               |
| Test Status                       | Done <input type="checkbox"/> |
| Reported Text Result              | 0.05                          |
| Reported Numeric Result           | 0.05                          |
| Reference Range low               | 0.00                          |
| Reference Range high              | 0.20                          |
| Range Units                       | X10^3/UL                      |
| Conventional Text Result          |                               |
| Conventional Numeric Result       |                               |
| Conventional Reference Range Low  |                               |
| Conventional Reference Range High |                               |
| Conventional Units                |                               |
| SI Text Result                    |                               |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (21)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (22)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

---

|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

---

|             |   |
|-------------|---|
| Subject Sex | F |
|-------------|---|

---

|                       |   |
|-----------------------|---|
| Subject Date of Birth | (b) (6)  |
|-----------------------|---|

---

|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | V225570 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 01 16 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:42 |
|------------------------|-------|

---

|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

---

|            |        |
|------------|--------|
| Battery ID | HM1604 |
|------------|--------|

---

|              |                                   |
|--------------|-----------------------------------|
| Battery Name | HEMATOLOGY<br>&DIFFERENTIAL PANEL |
|--------------|-----------------------------------|

---

|             |       |
|-------------|-------|
| Lab Test ID | HMT13 |
|-------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (22)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

|                                   |                               |
|-----------------------------------|-------------------------------|
| Lab Test Name                     | PLATELETS                     |
| Test ID                           |                               |
| Test Status                       | Done <input type="checkbox"/> |
| Reported Text Result              | 220                           |
| Reported Numeric Result           | 220                           |
| Reference Range low               | 140                           |
| Reference Range high              | 400                           |
| Range Units                       | X10^3/UL                      |
| Conventional Text Result          |                               |
| Conventional Numeric Result       |                               |
| Conventional Reference Range Low  |                               |
| Conventional Reference Range High |                               |
| Conventional Units                |                               |
| SI Text Result                    |                               |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (22)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (23)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

---

|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

---

|             |   |
|-------------|---|
| Subject Sex | F |
|-------------|---|

---

|                       |         |
|-----------------------|---------|
| Subject Date of Birth | (b) (6) |
|-----------------------|---------|

---

|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | V225570 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 01 16 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:42 |
|------------------------|-------|

---

|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

---

|            |        |
|------------|--------|
| Battery ID | HM1604 |
|------------|--------|

---

|              |                                   |
|--------------|-----------------------------------|
| Battery Name | HEMATOLOGY<br>&DIFFERENTIAL PANEL |
|--------------|-----------------------------------|

---

|             |       |
|-------------|-------|
| Lab Test ID | HMT15 |
|-------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (23)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

|                                   |  |
|-----------------------------------|--|
| Lab Test Name                     | NEUTROPHILS (%)                          |
| Test ID                           |  |
| Test Status                       | Done <input checked="" type="checkbox"/> |
| Reported Text Result              | 56.9                                     |
| Reported Numeric Result           | 56.9                                     |
| Reference Range low               | 40.5                                     |
| Reference Range high              | 75.0                                     |
| Range Units                       | %  |
| Conventional Text Result          |  |
| Conventional Numeric Result       |  |
| Conventional Reference Range Low  |  |
| Conventional Reference Range High |  |
| Conventional Units                |  |
| SI Text Result                    |  |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (23)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (24)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

---

|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

---

|             |   |
|-------------|---|
| Subject Sex | F |
|-------------|---|

---

|                       |   |
|-----------------------|---|
| Subject Date of Birth | (b) (6)  |
|-----------------------|---|

---

|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | V225570 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 01 16 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:42 |
|------------------------|-------|

---

|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

---

|            |        |
|------------|--------|
| Battery ID | HM1604 |
|------------|--------|

---

|              |                                   |
|--------------|-----------------------------------|
| Battery Name | HEMATOLOGY<br>&DIFFERENTIAL PANEL |
|--------------|-----------------------------------|

---

|             |       |
|-------------|-------|
| Lab Test ID | HMT16 |
|-------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (24)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

|                                   |                               |
|-----------------------------------|-------------------------------|
| Lab Test Name                     | LYMPHOCYTES (%)               |
| Test ID                           |                               |
| Test Status                       | Done <input type="checkbox"/> |
| Reported Text Result              | 32.4                          |
| Reported Numeric Result           | 32.4                          |
| Reference Range low               | 15.4                          |
| Reference Range high              | 48.5                          |
| Range Units                       | %                             |
| Conventional Text Result          |                               |
| Conventional Numeric Result       |                               |
| Conventional Reference Range Low  |                               |
| Conventional Reference Range High |                               |
| Conventional Units                |                               |
| SI Text Result                    |                               |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (24)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (25)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

---

|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

---

|             |   |
|-------------|---|
| Subject Sex | F |
|-------------|---|

---

|                       |   |
|-----------------------|---|
| Subject Date of Birth | (b) (6)  |
|-----------------------|---|

---

|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | V225570 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 01 16 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:42 |
|------------------------|-------|

---

|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

---

|            |        |
|------------|--------|
| Battery ID | HM1604 |
|------------|--------|

---

|              |                                   |
|--------------|-----------------------------------|
| Battery Name | HEMATOLOGY<br>&DIFFERENTIAL PANEL |
|--------------|-----------------------------------|

---

|             |       |
|-------------|-------|
| Lab Test ID | HMT17 |
|-------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (25)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

|                                   |  |
|-----------------------------------|--|
| Lab Test Name                     | MONOCYTES (%)                            |
| Test ID                           |  |
| Test Status                       | Done <input checked="" type="checkbox"/> |
| Reported Text Result              | 5.3                                      |
| Reported Numeric Result           | 5.3                                      |
| Reference Range low               | 2.6                                      |
| Reference Range high              | 10.1                                     |
| Range Units                       | %  |
| Conventional Text Result          |  |
| Conventional Numeric Result       |  |
| Conventional Reference Range Low  |  |
| Conventional Reference Range High |  |
| Conventional Units                |  |
| SI Text Result                    |  |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (25)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (26)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

---

|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

---

|             |   |
|-------------|---|
| Subject Sex | F |
|-------------|---|

---

|                       |   |
|-----------------------|---|
| Subject Date of Birth | (b) (6)  |
|-----------------------|---|

---

|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | V225570 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 01 16 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:42 |
|------------------------|-------|

---

|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

---

|            |        |
|------------|--------|
| Battery ID | HM1604 |
|------------|--------|

---

|              |                                   |
|--------------|-----------------------------------|
| Battery Name | HEMATOLOGY<br>&DIFFERENTIAL PANEL |
|--------------|-----------------------------------|

---

|             |       |
|-------------|-------|
| Lab Test ID | HMT18 |
|-------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (26)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

|                                   |  |
|-----------------------------------|--|
| Lab Test Name                     | EOSINOPHILS (%)                          |
| Test ID                           |  |
| Test Status                       | Done <input checked="" type="checkbox"/> |
| Reported Text Result              | 4.5                                      |
| Reported Numeric Result           | 4.5                                      |
| Reference Range low               | 0.0                                      |
| Reference Range high              | 6.8                                      |
| Range Units                       | %  |
| Conventional Text Result          |  |
| Conventional Numeric Result       |  |
| Conventional Reference Range Low  |  |
| Conventional Reference Range High |  |
| Conventional Units                |  |
| SI Text Result                    |  |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (26)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (27)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☒

---

Subject ID or Number 

---

---

Subject Sex F

---

Subject Date of Birth (b) (6)

---

Visit Name 

---

---

Visit Type Scheduled ☒

---

Accession ID V225570

---

Actual Collection Date 2014 01 16

---

Actual Collection Time 06:42

---

Specimen Condition 

---

---

Battery ID HM1604

---

Battery Name HEMATOLOGY  
&DIFFERENTIAL PANEL

---

Lab Test ID HMT19

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (27)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

|                                   |  |
|-----------------------------------|--|
| Lab Test Name                     | BASOPHILS (%)                            |
| Test ID                           |  |
| Test Status                       | Done <input checked="" type="checkbox"/> |
| Reported Text Result              | 0.9                                      |
| Reported Numeric Result           | 0.9                                      |
| Reference Range low               | 0.0                                      |
| Reference Range high              | 2.0                                      |
| Range Units                       | %  |
| Conventional Text Result          |  |
| Conventional Numeric Result       |  |
| Conventional Reference Range Low  |  |
| Conventional Reference Range High |  |
| Conventional Units                |  |
| SI Text Result                    |  |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (27)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (28)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

---

|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

---

|             |   |
|-------------|---|
| Subject Sex | F |
|-------------|---|

---

|                       |         |
|-----------------------|---------|
| Subject Date of Birth | (b) (6) |
|-----------------------|---------|

---

|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | V225570 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 01 16 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:42 |
|------------------------|-------|

---

|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

---

|            |        |
|------------|--------|
| Battery ID | HM1604 |
|------------|--------|

---

|              |                                   |
|--------------|-----------------------------------|
| Battery Name | HEMATOLOGY<br>&DIFFERENTIAL PANEL |
|--------------|-----------------------------------|

---

|             |      |
|-------------|------|
| Lab Test ID | HMT2 |
|-------------|------|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (28)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | HEMATOCRIT                            |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 38                                    |
| Reported Numeric Result           | 38                                    |
| Reference Range low               | 34                                    |
| Reference Range high              | 48                                    |
| Range Units                       | %                                     |
| Conventional Text Result          |                                       |
| Conventional Numeric Result       |                                       |
| Conventional Reference Range Low  |                                       |
| Conventional Reference Range High |                                       |
| Conventional Units                |                                       |
| SI Text Result                    |                                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (28)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (29)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

---

|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

---

|             |   |
|-------------|---|
| Subject Sex | F |
|-------------|---|

---

|                       |   |
|-----------------------|---|
| Subject Date of Birth | (b) (6)  |
|-----------------------|---|

---

|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | V225570 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 01 16 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:42 |
|------------------------|-------|

---

|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

---

|            |        |
|------------|--------|
| Battery ID | HM1604 |
|------------|--------|

---

|              |                                   |
|--------------|-----------------------------------|
| Battery Name | HEMATOLOGY<br>&DIFFERENTIAL PANEL |
|--------------|-----------------------------------|

---

|             |      |
|-------------|------|
| Lab Test ID | HMT3 |
|-------------|------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (29)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

|                                   |                            |
|-----------------------------------|----------------------------|
| Lab Test Name                     | RBC                        |
| Test ID                           |                            |
| Test Status                       | Done <input type="radio"/> |
| Reported Text Result              | 4.2                        |
| Reported Numeric Result           | 4.2                        |
| Reference Range low               | 4.1                        |
| Reference Range high              | 5.6                        |
| Range Units                       | X10^6/UL                   |
| Conventional Text Result          |                            |
| Conventional Numeric Result       |                            |
| Conventional Reference Range Low  |                            |
| Conventional Reference Range High |                            |
| Conventional Units                |                            |
| SI Text Result                    |                            |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (29)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (30)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☒

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6) 

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☒

---

Accession ID V225570

---

Actual Collection Date 2014 01 16

---

Actual Collection Time 06:42

---

Specimen Condition \_\_\_\_\_

---

Battery ID HM1604

---

Battery Name HEMATOLOGY  
&DIFFERENTIAL PANEL

---

Lab Test ID HMT4

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (30)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

|                                   |                            |
|-----------------------------------|----------------------------|
| Lab Test Name                     | MCV                        |
| Test ID                           |                            |
| Test Status                       | Done <input type="radio"/> |
| Reported Text Result              | 91                         |
| Reported Numeric Result           | 91                         |
| Reference Range low               | 79                         |
| Reference Range high              | 98                         |
| Range Units                       | FL                         |
| Conventional Text Result          |                            |
| Conventional Numeric Result       |                            |
| Conventional Reference Range Low  |                            |
| Conventional Reference Range High |                            |
| Conventional Units                |                            |
| SI Text Result                    |                            |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (30)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (31)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

---

|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

---

|             |   |
|-------------|---|
| Subject Sex | F |
|-------------|---|

---

|                       |         |
|-----------------------|---------|
| Subject Date of Birth | (b) (6) |
|-----------------------|---------|

---

|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | V225570 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 01 16 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:42 |
|------------------------|-------|

---

|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

---

|            |        |
|------------|--------|
| Battery ID | HM1604 |
|------------|--------|

---

|              |                                   |
|--------------|-----------------------------------|
| Battery Name | HEMATOLOGY<br>&DIFFERENTIAL PANEL |
|--------------|-----------------------------------|

---

|             |       |
|-------------|-------|
| Lab Test ID | HMT40 |
|-------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (31)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

|                                   |  |
|-----------------------------------|--|
| Lab Test Name                     | HEMOGLOBIN                               |
| Test ID                           |  |
| Test Status                       | Done <input checked="" type="checkbox"/> |
| Reported Text Result              | 12.5                                     |
| Reported Numeric Result           | 12.5                                     |
| Reference Range low               | 11.6                                     |
| Reference Range high              | 16.4                                     |
| Range Units                       | G/DL                                     |
| Conventional Text Result          |  |
| Conventional Numeric Result       |  |
| Conventional Reference Range Low  |  |
| Conventional Reference Range High |  |
| Conventional Units                |  |
| SI Text Result                    |  |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (31)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (32)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

---

|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

---

|             |   |
|-------------|---|
| Subject Sex | F |
|-------------|---|

---

|                       |         |
|-----------------------|---------|
| Subject Date of Birth | (b) (6) |
|-----------------------|---------|

---

|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | V225570 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 01 16 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:42 |
|------------------------|-------|

---

|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

---

|            |        |
|------------|--------|
| Battery ID | HM1604 |
|------------|--------|

---

|              |                                   |
|--------------|-----------------------------------|
| Battery Name | HEMATOLOGY<br>&DIFFERENTIAL PANEL |
|--------------|-----------------------------------|

---

|             |      |
|-------------|------|
| Lab Test ID | HMT7 |
|-------------|------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (32)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | WBC                                   |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 6.13                                  |
| Reported Numeric Result           | 6.13                                  |
| Reference Range low               | 3.80                                  |
| Reference Range high              | 10.70                                 |
| Range Units                       | X10^3/UL                              |
| Conventional Text Result          |                                       |
| Conventional Numeric Result       |                                       |
| Conventional Reference Range Low  |                                       |
| Conventional Reference Range High |                                       |
| Conventional Units                |                                       |
| SI Text Result                    |                                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (32)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (33)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

---

|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

---

|             |   |
|-------------|---|
| Subject Sex | F |
|-------------|---|

---

|                       |         |
|-----------------------|---------|
| Subject Date of Birth | (b) (6) |
|-----------------------|---------|

---

|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | V225570 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 01 16 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:42 |
|------------------------|-------|

---

|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

---

|            |        |
|------------|--------|
| Battery ID | HM1604 |
|------------|--------|

---

|              |                                   |
|--------------|-----------------------------------|
| Battery Name | HEMATOLOGY<br>&DIFFERENTIAL PANEL |
|--------------|-----------------------------------|

---

|             |       |
|-------------|-------|
| Lab Test ID | HMT71 |
|-------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (33)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

Lab Test Name


RBC MORPHOLOGY 1

---

Test ID

---

Test Status

Done 

---

Reported Text Result

NORMOCYTIC

---

Reported Numeric Result

---

Reference Range low

---

Reference Range high

---

Range Units

---

Conventional Text Result

---

Conventional Numeric Result

---

Conventional Reference Range Low

---

Conventional Reference Range High

---

Conventional Units

---

SI Text Result

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (33)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (34)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☒

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6)

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☒

---

Accession ID V225570

---

Actual Collection Date 2014 01 16

---

Actual Collection Time 06:42

---

Specimen Condition \_\_\_\_\_

---

Battery ID HM1604

---

Battery Name HEMATOLOGY  
&DIFFERENTIAL PANEL

---

Lab Test ID HMT8

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (34)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

|                                   |                            |
|-----------------------------------|----------------------------|
| Lab Test Name                     | NEUTROPHILS                |
| Test ID                           |                            |
| Test Status                       | Done <input type="radio"/> |
| Reported Text Result              | 3.49                       |
| Reported Numeric Result           | 3.49                       |
| Reference Range low               | 1.96                       |
| Reference Range high              | 7.23                       |
| Range Units                       | X10^3/UL                   |
| Conventional Text Result          |                            |
| Conventional Numeric Result       |                            |
| Conventional Reference Range Low  |                            |
| Conventional Reference Range High |                            |
| Conventional Units                |                            |
| SI Text Result                    |                            |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (34)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (35)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

---

|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

---

|             |   |
|-------------|---|
| Subject Sex | F |
|-------------|---|

---

|                       |         |
|-----------------------|---------|
| Subject Date of Birth | (b) (6) |
|-----------------------|---------|

---

|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | V225570 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 01 16 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:42 |
|------------------------|-------|

---

|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

---

|            |        |
|------------|--------|
| Battery ID | HM1604 |
|------------|--------|

---

|              |                                   |
|--------------|-----------------------------------|
| Battery Name | HEMATOLOGY<br>&DIFFERENTIAL PANEL |
|--------------|-----------------------------------|

---

|             |      |
|-------------|------|
| Lab Test ID | HMT9 |
|-------------|------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (35)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | LYMPHOCYTES                           |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 1.99                                  |
| Reported Numeric Result           | 1.99                                  |
| Reference Range low               | 0.91                                  |
| Reference Range high              | 4.28                                  |
| Range Units                       | X10^3/UL                              |
| Conventional Text Result          |                                       |
| Conventional Numeric Result       |                                       |
| Conventional Reference Range Low  |                                       |
| Conventional Reference Range High |                                       |
| Conventional Units                |                                       |
| SI Text Result                    |                                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (35)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (36)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

---

|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

---

|             |   |
|-------------|---|
| Subject Sex | F |
|-------------|---|

---

|                       |   |
|-----------------------|---|
| Subject Date of Birth | (b) (6)  |
|-----------------------|---|

---

|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | V225570 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 01 16 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:42 |
|------------------------|-------|

---

|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

---

|            |        |
|------------|--------|
| Battery ID | UA1538 |
|------------|--------|

---

|              |                   |
|--------------|-------------------|
| Battery Name | URINE MACRO PANEL |
|--------------|-------------------|

---

|             |       |
|-------------|-------|
| Lab Test ID | UAT10 |
|-------------|-------|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (36)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

Lab Test Name


UR NITRITE

---

Test ID

---

Test Status

Done 

---

Reported Text Result

NEGATIVE

---

Reported Numeric Result

---

Reference Range low

---

Reference Range high

---

Range Units

---

Conventional Text Result

---

Conventional Numeric Result

---

Conventional Reference Range Low

---

Conventional Reference Range High

---

Conventional Units

---

SI Text Result

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (36)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (37)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

---

|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

---

|             |   |
|-------------|---|
| Subject Sex | F |
|-------------|---|

---

|                       |         |
|-----------------------|---------|
| Subject Date of Birth | (b) (6) |
|-----------------------|---------|

---

|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | V225570 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 01 16 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:42 |
|------------------------|-------|

---

|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

---

|            |        |
|------------|--------|
| Battery ID | UA1538 |
|------------|--------|

---

|              |                   |
|--------------|-------------------|
| Battery Name | URINE MACRO PANEL |
|--------------|-------------------|

---

|             |      |
|-------------|------|
| Lab Test ID | UAT2 |
|-------------|------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (37)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

|                                   |                               |
|-----------------------------------|-------------------------------|
| Lab Test Name                     | UR SPECIFIC GRAVITY           |
| Test ID                           |                               |
| Test Status                       | Done <input type="checkbox"/> |
| Reported Text Result              | 1.014                         |
| Reported Numeric Result           | 1.014                         |
| Reference Range low               | 1.003                         |
| Reference Range high              | 1.035                         |
| Range Units                       |                               |
| Conventional Text Result          |                               |
| Conventional Numeric Result       |                               |
| Conventional Reference Range Low  |                               |
| Conventional Reference Range High |                               |
| Conventional Units                |                               |
| SI Text Result                    |                               |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (37)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (38)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☐

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6) 

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225570

---

Actual Collection Date 2014 01 16

---

Actual Collection Time 06:42

---

Specimen Condition \_\_\_\_\_

---

Battery ID UA1538

---

Battery Name URINE MACRO PANEL

---

Lab Test ID UAT3

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (38)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | UR PH                                 |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 5.0                                   |
| Reported Numeric Result           | 5.0                                   |
| Reference Range low               | 5.0                                   |
| Reference Range high              | 8.0                                   |
| Range Units                       |                                       |
| Conventional Text Result          |                                       |
| Conventional Numeric Result       |                                       |
| Conventional Reference Range Low  |                                       |
| Conventional Reference Range High |                                       |
| Conventional Units                |                                       |
| SI Text Result                    |                                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (38)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (39)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☒

---

Subject ID or Number 

---

---

Subject Sex F

---

Subject Date of Birth (b) (6) 

---

Visit Name 

---

---

Visit Type Scheduled ☒

---

Accession ID V225570

---

Actual Collection Date 2014 01 16

---

Actual Collection Time 06:42

---

Specimen Condition 

---

---

Battery ID UA1538

---

Battery Name URINE MACRO PANEL

---

Lab Test ID UAT43

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (39)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

Lab Test Name


UR BLOOD

---

Test ID

---

Test Status

Done 

---

Reported Text Result

NEGATIVE

---

Reported Numeric Result

---

Reference Range low

---

Reference Range high

---

Range Units

---

Conventional Text Result

---

Conventional Numeric Result

---

Conventional Reference Range Low

---

Conventional Reference Range High

---

Conventional Units

---

SI Text Result

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (39)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (40)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☐

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6) 

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225570

---

Actual Collection Date 2014 01 16

---

Actual Collection Time 06:42

---

Specimen Condition \_\_\_\_\_

---

Battery ID UA1538

---

Battery Name URINE MACRO PANEL

---

Lab Test ID UAT49

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (40)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

|                                   |                            |
|-----------------------------------|----------------------------|
| Lab Test Name                     | UR PROTEIN                 |
| Test ID                           |                            |
| Test Status                       | Done <input type="radio"/> |
| Reported Text Result              | NEGATIVE                   |
| Reported Numeric Result           |                            |
| Reference Range low               |                            |
| Reference Range high              |                            |
| Range Units                       |                            |
| Conventional Text Result          |                            |
| Conventional Numeric Result       |                            |
| Conventional Reference Range Low  |                            |
| Conventional Reference Range High |                            |
| Conventional Units                |                            |
| SI Text Result                    |                            |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (40)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (41)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☒

---

Subject ID or Number 

---

---

Subject Sex F

---

Subject Date of Birth (b) (6) 

---

Visit Name 

---

---

Visit Type Scheduled ☒

---

Accession ID V225570

---

Actual Collection Date 2014 01 16

---

Actual Collection Time 06:42

---

Specimen Condition 

---

---

Battery ID UA1538

---

Battery Name URINE MACRO PANEL

---

Lab Test ID UAT5

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (41)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

Lab Test Name


UR GLUCOSE

---

Test ID

---

Test Status

Done 

---

Reported Text Result

NORMAL

---

Reported Numeric Result

---

Reference Range low

---

Reference Range high

---

Range Units

---

Conventional Text Result

---

Conventional Numeric Result

---

Conventional Reference Range Low

---

Conventional Reference Range High

---

Conventional Units

---

SI Text Result

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (41)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (42)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☒

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6) ☒

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☒

---

Accession ID V225570

---

Actual Collection Date 2014 01 16

---

Actual Collection Time 06:42

---

Specimen Condition \_\_\_\_\_

---

Battery ID UA1538

---

Battery Name URINE MACRO PANEL

---

Lab Test ID UAT7

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (42)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

Lab Test Name


UR BILIRUBIN

---

Test ID

---

Test Status

Done 

---

Reported Text Result

NEGATIVE

---

Reported Numeric Result

---

Reference Range low

---

Reference Range high

---

Range Units

---

Conventional Text Result

---

Conventional Numeric Result

---

Conventional Reference Range Low

---

Conventional Reference Range High

---

Conventional Units

---

SI Text Result

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (42)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_COHB (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:50**

**Generated On: 20 Jul 2016 11:47:42**

|                               |                       |
|-------------------------------|-----------------------|
| Sample Barcode                | 05115150000098        |
| Analyte                       | CARBOXYHEMOGLOBIN     |
| Sample type                   | BLOOD                 |
| Result                        | .                     |
| Result Unit                   | %                     |
| Lab Status                    | OTHER                 |
| Sample comment                | ANALYSIS NOT REQUIRED |
| Detection method              | SPECTROPHOTOMETRIC    |
| Lower limit of quantification | 0.500                 |
| Planned time point (Hour)     | 6                     |
| Day of Visit                  | 0                     |
| Celerion Study Number         | AA99128-16            |
| Date of Collection            | 2014-JAN-16           |
| Timepoint-minutes             |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_COHB (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:50**

**Generated On: 20 Jul 2016 11:47:42**

---

Start Day (24 hour urine only) \_\_\_\_\_

---

End Day (24 hour Urine Only) \_\_\_\_\_

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_COHB (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:50**

**Generated On: 20 Jul 2016 11:47:42**

|                               |                       |
|-------------------------------|-----------------------|
| Sample Barcode                | 05115150000099        |
| Analyte                       | CARBOXYHEMOGLOBIN     |
| Sample type                   | BLOOD                 |
| Result                        | .                     |
| Result Unit                   | %                     |
| Lab Status                    | OTHER                 |
| Sample comment                | ANALYSIS NOT REQUIRED |
| Detection method              | SPECTROPHOTOMETRIC    |
| Lower limit of quantification | 0.500                 |
| Planned time point (Hour)     | 20                    |
| Day of Visit                  | 0                     |
| Celerion Study Number         | AA99128-16            |
| Date of Collection            | 2014-JAN-16           |
| Timepoint-minutes             |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_COHB (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:50**

**Generated On: 20 Jul 2016 11:47:42**

---

Start Day (24 hour urine only) \_\_\_\_\_

---

End Day (24 hour Urine Only) \_\_\_\_\_

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

Date of Birth

(b) (6)

---

Date of assessment

2014 JAN 16

DD/MMM/YYYY

DD/MMM/YYYY

---

Time of assessment

20:33

hour:min 24-hour clock

---

Assessment Status

Completed ☒

---

1. Was smoking satisfying?

Moderately ☒

---

2. Did cigarettes taste good?

Moderately ☒

---

3. Did you enjoy the sensation in your throat and chest?

Little ☒

---

4. Did smoking calm you down?

Moderately ☒

---

5. Did smoking make you feel more awake?

Moderately ☒

---

6. Did smoking make you feel less irritable?

Moderately ☒

---

7. Did smoking help you concentrate?

Very little ☒

---

8. Did smoking reduce your hunger for food?

Moderately ☒

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:18**

**Generated On: 20 Jul 2016 11:47:42**

---

9. Did smoking make you dizzy? Very little ☐

---

10. Did smoking make you nauseous? Not at all ☐

---

11. Did smoking immediately relieve your craving for a  
cigarette? A lot ☐

---

12. Did you enjoy smoking? Moderately ☐

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Human Smoking Topography Questionnaire**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:17**

**Generated On: 20 Jul 2016 11:47:42**

---

|      |  |
|------|--|
| Type | HUMAN SMOKING<br>TOPOGRAPHY<br>QUESTIONNAIRE |
|------|--|

---

|                               |                           |
|-------------------------------|---------------------------|
| Was paper questionnaire used? | Yes <input type="radio"/> |
|-------------------------------|---------------------------|

---

|                 |       |
|-----------------|-------|
| Reason not done | <hr/> |
|-----------------|-------|

---

|                    |                            |
|--------------------|----------------------------|
| Date of assessment | 16 JAN 2014<br>DD/MMM/YYYY |
|--------------------|----------------------------|

---

|                    |                                 |
|--------------------|---------------------------------|
| Time of assessment | 20:37<br>hour:min 24-hour clock |
|--------------------|---------------------------------|

---

How do you agree with the following sentences/affirmations :

---

|  |  |
|--|--|
| 1. The smoking of the conventional cigarettes/products is different with the device. | Neither agree nor disagree <input type="radio"/> |
|--|--|

---

|   |       |
|---|-------|
| If you agree or strongly agree, please describe : | <hr/> |
|---|-------|

---

|   |  |
|---|--|
| 2. You enjoy smoking with the device as much as without it. | Neither agree nor disagree <input type="radio"/> |
|---|--|

---

|   |       |
|---|-------|
| If you disagree or strongly disagree, please describe : | <hr/> |
|---|-------|

---

|  |                                |
|--|--------------------------------|
| 3. The taste of the conventional cigarettes/products is different with the device. | Disagree <input type="radio"/> |
|--|--------------------------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Human Smoking Topography Questionnaire**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:17**

**Generated On: 20 Jul 2016 11:47:42**

---

If you agree or strongly agree, please describe : DOES NOT EFFECT TASTE

---

4. The device is easy to use. Strongly agree ☒

---

If you disagree or strongly disagree, please describe : \_\_\_\_\_

---

5. Your smoking is disturbed by the device. Strongly disagree ☒

---

If you agree or strongly agree, please describe : \_\_\_\_\_

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Questionnaire on smoking urges (QSU)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:17**

**Generated On: 20 Jul 2016 11:47:42**

---

|      |     |
|------|-----|
| Type | QSU |
|------|-----|

---

|               |         |
|---------------|---------|
| Date of Birth | (b) (6) |
|---------------|---------|

---

|                    |             |
|--------------------|-------------|
| Date of assessment | 2014 JAN 16 |
|--------------------|-------------|

DD/MMM/YYYY

---

|                    |       |
|--------------------|-------|
| Time of assessment | 20:32 |
|--------------------|-------|

hour:min 24-hour clock

---

|                   |                                 |
|-------------------|---------------------------------|
| Assessment Status | Completed <input type="radio"/> |
|-------------------|---------------------------------|

---

|  |  |
|--|--|
| 1. I have a desire for a cigarette right now | Do not agree or disagree <input type="radio"/> |
|--|--|

---

|   |   |
|---|---|
| 2. Nothing would be better than smoking a cigarette right now | Somewhat disagree <input type="radio"/> |
|---|---|

---

|   |                             |
|---|-----------------------------|
| 3. If it were possible I would probably smoke now | Agree <input type="radio"/> |
|---|-----------------------------|

---

|   |                                |
|---|--------------------------------|
| 4. I could control things better right now if I could smoke | Disagree <input type="radio"/> |
|---|--------------------------------|

---

|  |  |
|--|--|
| 5. All I want right now is a cigarette | Do not agree or disagree <input type="radio"/> |
|--|--|

---

|                                   |                             |
|-----------------------------------|-----------------------------|
| 6. I have an urge for a cigarette | Agree <input type="radio"/> |
|-----------------------------------|-----------------------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Questionnaire on smoking urges (QSU)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:17**

**Generated On: 20 Jul 2016 11:47:42**

---

7. A cigarette would taste good now Agree ☐

---

8. I would do almost anything for a cigarette now Somewhat disagree ☐

---

9. Smoking would make me less depressed Strongly disagree ☐

---

10. I am going to smoke as soon as possible Agree ☐

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:45**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

---

|                      |      |
|----------------------|------|
| Subject ID or Number | 1042 |
|----------------------|------|

---

|             |   |
|-------------|---|
| Subject Sex | F |
|-------------|---|

---

|                       |         |
|-----------------------|---------|
| Subject Date of Birth | (b) (6) |
|-----------------------|---------|

---

|            |      |
|------------|------|
| Visit Name | DAY0 |
|------------|------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | V225570 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 01 16 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:42 |
|------------------------|-------|

---

|                    |  |
|--------------------|--|
| Specimen Condition |  |
|--------------------|--|

---

|            |        |
|------------|--------|
| Battery ID | HM1054 |
|------------|--------|

---

|              |                |
|--------------|----------------|
| Battery Name | HEMOGLOBIN A1C |
|--------------|----------------|

---

|             |        |
|-------------|--------|
| Lab Test ID | HMT370 |
|-------------|--------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:45**

**Generated On: 20 Jul 2016 11:47:42**

---

Lab Test Name


HEMOGLOBIN  
A1C,VARIANT(-70)

---

Test ID

---

Test Status

Done 

---

Reported Text Result

5.3

---

Reported Numeric Result

5.3

---

Reference Range low

---

Reference Range high

<6.5

---

Range Units

%

---

Conventional Text Result

---

Conventional Numeric Result

---

Conventional Reference Range Low

---

Conventional Reference Range High

---

Conventional Units

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:45**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Text Result

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:45**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

---

|                      |      |
|----------------------|------|
| Subject ID or Number | 1042 |
|----------------------|------|

---

|             |   |
|-------------|---|
| Subject Sex | F |
|-------------|---|

---

|                       |         |
|-----------------------|---------|
| Subject Date of Birth | (b) (6) |
|-----------------------|---------|

---

|            |      |
|------------|------|
| Visit Name | DAY0 |
|------------|------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | V225570 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 01 16 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:42 |
|------------------------|-------|

---

|                    |  |
|--------------------|--|
| Specimen Condition |  |
|--------------------|--|

---

|            |        |
|------------|--------|
| Battery ID | RC6871 |
|------------|--------|

---

|              |     |
|--------------|-----|
| Battery Name | HDL |
|--------------|-----|

---

|             |         |
|-------------|---------|
| Lab Test ID | RCT1684 |
|-------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:45**

**Generated On: 20 Jul 2016 11:47:42**

|                                   |                                |
|-----------------------------------|--------------------------------|
| Lab Test Name                     | DIRECT HDL-C 3RD<br>GENERATION |
| Test ID                           |                                |
| Test Status                       | Done <input type="radio"/>     |
| Reported Text Result              | 74                             |
| Reported Numeric Result           | 74                             |
| Reference Range low               | 34                             |
| Reference Range high              | 87                             |
| Range Units                       | MG/DL                          |
| Conventional Text Result          |                                |
| Conventional Numeric Result       |                                |
| Conventional Reference Range Low  |                                |
| Conventional Reference Range High |                                |
| Conventional Units                |                                |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:45**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Text Result

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:45**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

---

|                      |      |
|----------------------|------|
| Subject ID or Number | 1042 |
|----------------------|------|

---

|             |   |
|-------------|---|
| Subject Sex | F |
|-------------|---|

---

|                       |         |
|-----------------------|---------|
| Subject Date of Birth | (b) (6) |
|-----------------------|---------|

---

|            |      |
|------------|------|
| Visit Name | DAY0 |
|------------|------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | V225570 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 01 16 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:42 |
|------------------------|-------|

---

|                    |  |
|--------------------|--|
| Specimen Condition |  |
|--------------------|--|

---

|            |        |
|------------|--------|
| Battery ID | SC3249 |
|------------|--------|

---

|              |        |
|--------------|--------|
| Battery Name | HS-CRP |
|--------------|--------|

---

|             |         |
|-------------|---------|
| Lab Test ID | SCT1528 |
|-------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:45**

**Generated On: 20 Jul 2016 11:47:42**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | C-REACTIVE PROTEIN (NHS)-QT           |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 0.104                                 |
| Reported Numeric Result           | 0.104                                 |
| Reference Range low               |                                       |
| Reference Range high              | <=0.287                               |
| Range Units                       | MG/DL                                 |
| Conventional Text Result          |                                       |
| Conventional Numeric Result       |                                       |
| Conventional Reference Range Low  |                                       |
| Conventional Reference Range High |                                       |
| Conventional Units                |                                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:45**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Text Result

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:45**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |                                  |
|-------------------|----------------------------------|
| Transmission Type | Cumulative <input type="radio"/> |
|-------------------|----------------------------------|

---

|                      |      |
|----------------------|------|
| Subject ID or Number | 1042 |
|----------------------|------|

---

|             |   |
|-------------|---|
| Subject Sex | F |
|-------------|---|

---

|                       |         |
|-----------------------|---------|
| Subject Date of Birth | (b) (6) |
|-----------------------|---------|

---

|            |      |
|------------|------|
| Visit Name | DAY0 |
|------------|------|

---

|            |                                 |
|------------|---------------------------------|
| Visit Type | Scheduled <input type="radio"/> |
|------------|---------------------------------|

---

|              |         |
|--------------|---------|
| Accession ID | V225570 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 01 16 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:42 |
|------------------------|-------|

---

|                    |  |
|--------------------|--|
| Specimen Condition |  |
|--------------------|--|

---

|            |        |
|------------|--------|
| Battery ID | SC3582 |
|------------|--------|

---

|              |                |
|--------------|----------------|
| Battery Name | APOLIPOPROTEIN |
|--------------|----------------|

---

|             |         |
|-------------|---------|
| Lab Test ID | SCT3639 |
|-------------|---------|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:45**

**Generated On: 20 Jul 2016 11:47:42**

---

|               |                         |
|---------------|-------------------------|
| Lab Test Name | APOLIPOPROTEIN A1, RAND |
|---------------|-------------------------|

---

|         |       |
|---------|-------|
| Test ID | <hr/> |
|---------|-------|

---

|             |                                       |
|-------------|---------------------------------------|
| Test Status | Done <input checked="" type="radio"/> |
|-------------|---------------------------------------|

---

|                      |     |
|----------------------|-----|
| Reported Text Result | 160 |
|----------------------|-----|

---

|                         |     |
|-------------------------|-----|
| Reported Numeric Result | 160 |
|-------------------------|-----|

---

|                     |     |
|---------------------|-----|
| Reference Range low | 125 |
|---------------------|-----|

---

|                      |     |
|----------------------|-----|
| Reference Range high | 215 |
|----------------------|-----|

---

|             |       |
|-------------|-------|
| Range Units | MG/DL |
|-------------|-------|

---

|                          |       |
|--------------------------|-------|
| Conventional Text Result | <hr/> |
|--------------------------|-------|

---

|                             |       |
|-----------------------------|-------|
| Conventional Numeric Result | <hr/> |
|-----------------------------|-------|

---

|                                  |       |
|----------------------------------|-------|
| Conventional Reference Range Low | <hr/> |
|----------------------------------|-------|

---

|                                   |       |
|-----------------------------------|-------|
| Conventional Reference Range High | <hr/> |
|-----------------------------------|-------|

---

|                    |       |
|--------------------|-------|
| Conventional Units | <hr/> |
|--------------------|-------|

---

|                |       |
|----------------|-------|
| SI Text Result | <hr/> |
|----------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:45**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:45**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

---

|                      |      |
|----------------------|------|
| Subject ID or Number | 1042 |
|----------------------|------|

---

|             |   |
|-------------|---|
| Subject Sex | F |
|-------------|---|

---

|                       |         |
|-----------------------|---------|
| Subject Date of Birth | (b) (6) |
|-----------------------|---------|

---

|            |      |
|------------|------|
| Visit Name | DAY0 |
|------------|------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | V225570 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 01 16 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:42 |
|------------------------|-------|

---

|                    |  |
|--------------------|--|
| Specimen Condition |  |
|--------------------|--|

---

|            |        |
|------------|--------|
| Battery ID | SC3582 |
|------------|--------|

---

|              |                |
|--------------|----------------|
| Battery Name | APOLIPOPROTEIN |
|--------------|----------------|

---

|             |         |
|-------------|---------|
| Lab Test ID | SCT3643 |
|-------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:45**

**Generated On: 20 Jul 2016 11:47:42**

|                                   |  |
|-----------------------------------|--|
| Lab Test Name                     | APOLIPOPROTEIN B, RAND                   |
| Test ID                           |  |
| Test Status                       | Done <input checked="" type="checkbox"/> |
| Reported Text Result              | 73                                       |
| Reported Numeric Result           | 73                                       |
| Reference Range low               | 55                                       |
| Reference Range high              | 125                                      |
| Range Units                       | MG/DL                                    |
| Conventional Text Result          |  |
| Conventional Numeric Result       |  |
| Conventional Reference Range Low  |  |
| Conventional Reference Range High |  |
| Conventional Units                |  |
| SI Text Result                    |  |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:45**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:45**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

---

|                      |      |
|----------------------|------|
| Subject ID or Number | 1042 |
|----------------------|------|

---

|             |   |
|-------------|---|
| Subject Sex | F |
|-------------|---|

---

|                       |         |
|-----------------------|---------|
| Subject Date of Birth | (b) (6) |
|-----------------------|---------|

---

|            |      |
|------------|------|
| Visit Name | DAY0 |
|------------|------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | V225570 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 01 16 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:42 |
|------------------------|-------|

---

|                    |  |
|--------------------|--|
| Specimen Condition |  |
|--------------------|--|

---

|            |       |
|------------|-------|
| Battery ID | CG267 |
|------------|-------|

---

|              |            |
|--------------|------------|
| Battery Name | FIBRINOGEN |
|--------------|------------|

---

|             |        |
|-------------|--------|
| Lab Test ID | CGT285 |
|-------------|--------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:45**

**Generated On: 20 Jul 2016 11:47:42**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | FIBRINOGEN                            |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 317                                   |
| Reported Numeric Result           | 317                                   |
| Reference Range low               | 200                                   |
| Reference Range high              | 400                                   |
| Range Units                       | MG/DL                                 |
| Conventional Text Result          |                                       |
| Conventional Numeric Result       |                                       |
| Conventional Reference Range Low  |                                       |
| Conventional Reference Range High |                                       |
| Conventional Units                |                                       |
| SI Text Result                    |                                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:45**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (7)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:45**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

---

|                      |      |
|----------------------|------|
| Subject ID or Number | 1042 |
|----------------------|------|

---

|             |   |
|-------------|---|
| Subject Sex | F |
|-------------|---|

---

|                       |         |
|-----------------------|---------|
| Subject Date of Birth | (b) (6) |
|-----------------------|---------|

---

|            |      |
|------------|------|
| Visit Name | DAY0 |
|------------|------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | V225570 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 01 16 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:42 |
|------------------------|-------|

---

|                    |  |
|--------------------|--|
| Specimen Condition |  |
|--------------------|--|

---

|            |       |
|------------|-------|
| Battery ID | CN236 |
|------------|-------|

---

|              |              |
|--------------|--------------|
| Battery Name | HOMOCYSTEINE |
|--------------|--------------|

---

|             |        |
|-------------|--------|
| Lab Test ID | CNT145 |
|-------------|--------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (7)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:45**

**Generated On: 20 Jul 2016 11:47:42**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | HOMOCYSTEINE, EDTAPL                  |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 8.34                                  |
| Reported Numeric Result           | 8.34                                  |
| Reference Range low               | 3.70                                  |
| Reference Range high              | 13.90                                 |
| Range Units                       | UMOL/L                                |
| Conventional Text Result          |                                       |
| Conventional Numeric Result       |                                       |
| Conventional Reference Range Low  |                                       |
| Conventional Reference Range High |                                       |
| Conventional Units                |                                       |
| SI Text Result                    |                                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (7)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:45**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (8)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:45**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

---

|                      |      |
|----------------------|------|
| Subject ID or Number | 1042 |
|----------------------|------|

---

|             |   |
|-------------|---|
| Subject Sex | F |
|-------------|---|

---

|                       |         |
|-----------------------|---------|
| Subject Date of Birth | (b) (6) |
|-----------------------|---------|

---

|            |      |
|------------|------|
| Visit Name | DAY0 |
|------------|------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | V225570 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 01 16 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:42 |
|------------------------|-------|

---

|                    |  |
|--------------------|--|
| Specimen Condition |  |
|--------------------|--|

---

|            |        |
|------------|--------|
| Battery ID | IM2293 |
|------------|--------|

---

|              |         |
|--------------|---------|
| Battery Name | SICAM-1 |
|--------------|---------|

---

|             |         |
|-------------|---------|
| Lab Test ID | IMT1768 |
|-------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (8)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:45**

**Generated On: 20 Jul 2016 11:47:42**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | SICAM-1-RUO                           |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 477.0                                 |
| Reported Numeric Result           | 477.0                                 |
| Reference Range low               | 98.8                                  |
| Reference Range high              | 320.0                                 |
| Range Units                       | NG/ML                                 |
| Conventional Text Result          |                                       |
| Conventional Numeric Result       |                                       |
| Conventional Reference Range Low  |                                       |
| Conventional Reference Range High |                                       |
| Conventional Units                |                                       |
| SI Text Result                    |                                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (8)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:45**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---


SI Units

---

Reported Result Type

---

Alert Flag

High 

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (9)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:45**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

---

|                      |      |
|----------------------|------|
| Subject ID or Number | 1042 |
|----------------------|------|

---

|             |   |
|-------------|---|
| Subject Sex | F |
|-------------|---|

---

|                       |         |
|-----------------------|---------|
| Subject Date of Birth | (b) (6) |
|-----------------------|---------|

---

|            |      |
|------------|------|
| Visit Name | DAY0 |
|------------|------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | V225570 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 01 16 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:42 |
|------------------------|-------|

---

|                    |  |
|--------------------|--|
| Specimen Condition |  |
|--------------------|--|

---

|            |        |
|------------|--------|
| Battery ID | RC9267 |
|------------|--------|

---

|              |     |
|--------------|-----|
| Battery Name | LDL |
|--------------|-----|

---

|             |         |
|-------------|---------|
| Lab Test ID | RCT2394 |
|-------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (9)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:45**

**Generated On: 20 Jul 2016 11:47:42**

---

|               |                            |
|---------------|----------------------------|
| Lab Test Name | DIRECT LDL-C 2ND GEN (-70) |
|---------------|----------------------------|

---

|         |       |
|---------|-------|
| Test ID | <hr/> |
|---------|-------|

---

|             |                                       |
|-------------|---------------------------------------|
| Test Status | Done <input checked="" type="radio"/> |
|-------------|---------------------------------------|

---

|                      |    |
|----------------------|----|
| Reported Text Result | 84 |
|----------------------|----|

---

|                         |    |
|-------------------------|----|
| Reported Numeric Result | 84 |
|-------------------------|----|

---

|                     |    |
|---------------------|----|
| Reference Range low | 80 |
|---------------------|----|

---

|                      |     |
|----------------------|-----|
| Reference Range high | 187 |
|----------------------|-----|

---

|             |       |
|-------------|-------|
| Range Units | MG/DL |
|-------------|-------|

---

|                          |       |
|--------------------------|-------|
| Conventional Text Result | <hr/> |
|--------------------------|-------|

---

|                             |       |
|-----------------------------|-------|
| Conventional Numeric Result | <hr/> |
|-----------------------------|-------|

---

|                                  |       |
|----------------------------------|-------|
| Conventional Reference Range Low | <hr/> |
|----------------------------------|-------|

---

|                                   |       |
|-----------------------------------|-------|
| Conventional Reference Range High | <hr/> |
|-----------------------------------|-------|

---

|                    |       |
|--------------------|-------|
| Conventional Units | <hr/> |
|--------------------|-------|

---

|                |       |
|----------------|-------|
| SI Text Result | <hr/> |
|----------------|-------|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (9)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:45**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (CEMA, HPMa, HBMA)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:50**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:50**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112450000091        |
| Analyte                   | HPMA                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 0                     |
| Celerion Study Number     | AA99128-03            |
| Date of Collection        | 2014-JAN-16           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 0                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:50**

**Generated On: 20 Jul 2016 11:47:42**

---

|               |   |
|---------------|---|
| Urine End Day | 1 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:50**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112450000091        |
| Analyte                   | CEMA                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 0                     |
| Celerion Study Number     | AA99128-03            |
| Date of Collection        | 2014-JAN-16           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 0                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:50**

**Generated On: 20 Jul 2016 11:47:42**

---

|               |   |
|---------------|---|
| Urine End Day | 1 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:50**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112450000091        |
| Analyte                   | HBMA                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 0                     |
| Celerion Study Number     | AA99128-03            |
| Date of Collection        | 2014-JAN-16           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 0                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (CEMA, HPMa, HBMA) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:50**

**Generated On: 20 Jul 2016 11:47:42**

---

|               |   |
|---------------|---|
| Urine End Day | 1 |
|---------------|---|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (NNN, NNAL)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:49**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (NNN, NNAL) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:49**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112460000091        |
| Analyte                   | NNAL                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | PG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 0                     |
| Celerion Study Number     | AA99128-04            |
| Date of Collection        | 2014-JAN-16           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 0                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (NNN, NNAL) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:49**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (NNN, NNAL) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:49**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112460000091        |
| Analyte                   | NNN                   |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | PG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 0                     |
| Celerion Study Number     | AA99128-04            |
| Date of Collection        | 2014-JAN-16           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 0                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (NNN, NNAL) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:49**

**Generated On: 20 Jul 2016 11:47:42**

---

|               |   |
|---------------|---|
| Urine End Day | 1 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (HEMA)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:49**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (HEMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:49**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112470000091        |
| Analyte                   | HEMA                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 0                     |
| Celerion Study Number     | AA99128-05            |
| Date of Collection        | 2014-JAN-16           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 0                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (HEMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:49**

**Generated On: 20 Jul 2016 11:47:42**

---

|               |   |
|---------------|---|
| Urine End Day | 1 |
|---------------|---|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:50**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:50**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112480000058        |
| Analyte                   | COT                   |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 0                     |
| Celerion Study Number     | AA99128-06            |
| Date of Collection        | 2014-JAN-17           |
| Timepoint-minutes         |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:50**

**Generated On: 20 Jul 2016 11:47:42**

---

|                 |   |
|-----------------|---|
| Urine Start Day | 0 |
| <hr/>           |   |
| Urine End Day   | 1 |
| <hr/>           |   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:50**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112480000058        |
| Analyte                   | COT-GLUC              |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 0                     |
| Celerion Study Number     | AA99128-06            |
| Date of Collection        | 2014-JAN-17           |
| Timepoint-minutes         |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:50**

**Generated On: 20 Jul 2016 11:47:42**

---

|                 |   |
|-----------------|---|
| Urine Start Day | 0 |
|-----------------|---|

---

|               |   |
|---------------|---|
| Urine End Day | 1 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:50**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112480000058        |
| Analyte                   | NIC                   |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 0                     |
| Celerion Study Number     | AA99128-06            |
| Date of Collection        | 2014-JAN-17           |
| Timepoint-minutes         |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:50**

**Generated On: 20 Jul 2016 11:47:42**

---

|                 |   |
|-----------------|---|
| Urine Start Day | 0 |
|-----------------|---|

---

|               |   |
|---------------|---|
| Urine End Day | 1 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:50**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112480000058        |
| Analyte                   | NIC-GLUC              |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 0                     |
| Celerion Study Number     | AA99128-06            |
| Date of Collection        | 2014-JAN-17           |
| Timepoint-minutes         |                       |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:50**

**Generated On: 20 Jul 2016 11:47:42**

---

|                 |   |
|-----------------|---|
| Urine Start Day | 0 |
|-----------------|---|

---

|               |   |
|---------------|---|
| Urine End Day | 1 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:50**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112480000058        |
| Analyte                   | THCOT                 |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 0                     |
| Celerion Study Number     | AA99128-06            |
| Date of Collection        | 2014-JAN-17           |
| Timepoint-minutes         |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:50**

**Generated On: 20 Jul 2016 11:47:42**

---

|                 |   |
|-----------------|---|
| Urine Start Day | 0 |
| <hr/>           |   |
| Urine End Day   | 1 |
| <hr/>           |   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:50**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112480000058        |
| Analyte                   | THCOT-GLUC            |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 0                     |
| Celerion Study Number     | AA99128-06            |
| Date of Collection        | 2014-JAN-17           |
| Timepoint-minutes         |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:50**

**Generated On: 20 Jul 2016 11:47:42**

---

|                 |   |
|-----------------|---|
| Urine Start Day | 0 |
| <hr/>           |   |
| Urine End Day   | 1 |
| <hr/>           |   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (3-OH BaP)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:51**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (3-OH BaP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:51**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112490000091        |
| Analyte                   | 3-OH BAP              |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | FG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 0                     |
| Celerion Study Number     | AA99128-07            |
| Date of Collection        | 2014-JAN-16           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 0                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (3-OH BaP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:51**

**Generated On: 20 Jul 2016 11:47:42**

---

|               |   |
|---------------|---|
| Urine End Day | 1 |
|---------------|---|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Plasma (Caffeine, Paraxanthine)**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

PLASMA

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Plasma (Caffeine, Paraxanthine) (1)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05112500000025 |
|----------------|----------------|

---

|         |          |
|---------|----------|
| Analyte | CAFFEINE |
|---------|----------|

---

|             |        |
|-------------|--------|
| Sample type | PLASMA |
|-------------|--------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |       |
|------------|-------|
| Lab Status | OTHER |
|------------|-------|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | ANALYSIS NOT REQUIRED |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 6 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 0 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-08 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-JAN-16 |
|--------------------|-------------|

---

|                   |   |
|-------------------|---|
| Timepoint-minutes | 0 |
|-------------------|---|

---

|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Plasma (Caffeine, Paraxanthine) (1)**

**Generated On: 20 Jul 2016 11:47:42**

---

|               |   |
|---------------|---|
| Urine End Day | 0 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Plasma (Caffeine, Paraxanthine) (2)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05112500000025 |
|----------------|----------------|

---

|         |              |
|---------|--------------|
| Analyte | PARAXANTHINE |
|---------|--------------|

---

|             |        |
|-------------|--------|
| Sample type | PLASMA |
|-------------|--------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |       |
|------------|-------|
| Lab Status | OTHER |
|------------|-------|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | ANALYSIS NOT REQUIRED |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 6 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 0 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-08 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-JAN-16 |
|--------------------|-------------|

---

|                   |   |
|-------------------|---|
| Timepoint-minutes | 0 |
|-------------------|---|

---

|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Plasma (Caffeine, Paraxanthine) (2)**

**Generated On: 20 Jul 2016 11:47:42**

---

|               |   |
|---------------|---|
| Urine End Day | 0 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:51**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:51**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112510000091        |
| Analyte                   | 1-NA                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | PG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 0                     |
| Celerion Study Number     | AA99128-09            |
| Date of Collection        | 2014-JAN-16           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 0                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:51**

**Generated On: 20 Jul 2016 11:47:42**

---

|               |   |
|---------------|---|
| Urine End Day | 1 |
|---------------|---|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:51**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112510000091        |
| Analyte                   | 2-NA                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | PG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 0                     |
| Celerion Study Number     | AA99128-09            |
| Date of Collection        | 2014-JAN-16           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 0                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:51**

**Generated On: 20 Jul 2016 11:47:42**

---

|               |   |
|---------------|---|
| Urine End Day | 1 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:51**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112510000091        |
| Analyte                   | 4-ABP                 |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | PG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 0                     |
| Celerion Study Number     | AA99128-09            |
| Date of Collection        | 2014-JAN-16           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 0                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:51**

**Generated On: 20 Jul 2016 11:47:42**

---

|               |   |
|---------------|---|
| Urine End Day | 1 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:51**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112510000091        |
| Analyte                   | O-TOL                 |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | PG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 0                     |
| Celerion Study Number     | AA99128-09            |
| Date of Collection        | 2014-JAN-16           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 0                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:51**

**Generated On: 20 Jul 2016 11:47:42**

---

|               |   |
|---------------|---|
| Urine End Day | 1 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (11-dTXb2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:49**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (11-dTXb2) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:49**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112530000059        |
| Analyte                   | 11-DTXB2              |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | PG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 0                     |
| Celerion Study Number     | AA99128-11            |
| Date of Collection        | 2014-JAN-16           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 0                     |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (11-dTXb2) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:49**

**Generated On: 20 Jul 2016 11:47:42**

---

|               |   |
|---------------|---|
| Urine End Day | 1 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (iPF2a-III)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:49**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (iPF2a-III) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:49**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112540000059        |
| Analyte                   | IPF2A-III             |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | PG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 0                     |
| Celerion Study Number     | AA99128-12            |
| Date of Collection        | 2014-JAN-16           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 0                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (iPF2a-III) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:49**

**Generated On: 20 Jul 2016 11:47:42**

---

|               |   |
|---------------|---|
| Urine End Day | 1 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Ames)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:51**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Ames) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:51**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05113320000022        |
| Analyte                   | AMES                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | REV/ML                |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | COUNT                 |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 0                     |
| Celerion Study Number     | AA99128-15            |
| Date of Collection        | 2014-JAN-16           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 0                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Ames) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:51**

**Generated On: 20 Jul 2016 11:47:42**

---

|               |   |
|---------------|---|
| Urine End Day | 1 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (1-OHP)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:51**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (1-OHP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:51**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05115190001180        |
| Analyte                   | 1-OHP                 |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | PG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 0                     |
| Celerion Study Number     | AA99598-03            |
| Date of Collection        | 2014-JAN-16           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 0                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (1-OHP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:51**

**Generated On: 20 Jul 2016 11:47:42**

---

|               |   |
|---------------|---|
| Urine End Day | 1 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (SPMA, SBMA)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:49**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (SPMA, SBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:49**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05115170000091        |
| Analyte                   | SBMA                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 0                     |
| Celerion Study Number     | AA99598-01            |
| Date of Collection        | 2014-JAN-16           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 0                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (SPMA, SBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:49**

**Generated On: 20 Jul 2016 11:47:42**

---

|               |   |
|---------------|---|
| Urine End Day | 1 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (SPMA, SBMA) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:49**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05115170000091        |
| Analyte                   | SPMA                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 0                     |
| Celerion Study Number     | AA99598-01            |
| Date of Collection        | 2014-JAN-16           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 0                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (SPMA, SBMA) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:49**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (MHBMA)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:50**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (MHBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:50**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05115180000091        |
| Analyte                   | MHBMA                 |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 0                     |
| Celerion Study Number     | AA99598-02            |
| Date of Collection        | 2014-JAN-16           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 0                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (MHBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:50**

**Generated On: 20 Jul 2016 11:47:42**

---

|               |   |
|---------------|---|
| Urine End Day | 1 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Creatinine)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:51**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Creatinine) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:51**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05115160000091        |
| Analyte                   | CREATININE            |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | MG/DL                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | SPECTROPHOTOMETRIC    |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 0                     |
| Celerion Study Number     | AA99128-14            |
| Date of Collection        | 2014-JAN-16           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 0                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Creatinine) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:51**

**Generated On: 20 Jul 2016 11:47:42**

---

|               |   |
|---------------|---|
| Urine End Day | 1 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Plasma (Nic, Cot, tHCot)**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

PLASMA

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05112430000096 |
|----------------|----------------|

---

|         |     |
|---------|-----|
| Analyte | COT |
|---------|-----|

---

|             |        |
|-------------|--------|
| Sample type | PLASMA |
|-------------|--------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |       |
|------------|-------|
| Lab Status | OTHER |
|------------|-------|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | ANALYSIS NOT REQUIRED |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 0 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-01 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-JAN-16 |
|--------------------|-------------|

---

|                   |   |
|-------------------|---|
| Timepoint-minutes | 0 |
|-------------------|---|

---

|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)**

**Generated On: 20 Jul 2016 11:47:42**

---

|               |   |
|---------------|---|
| Urine End Day | 0 |
|---------------|---|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05112430000096 |
|----------------|----------------|

---

|         |     |
|---------|-----|
| Analyte | NIC |
|---------|-----|

---

|             |        |
|-------------|--------|
| Sample type | PLASMA |
|-------------|--------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |       |
|------------|-------|
| Lab Status | OTHER |
|------------|-------|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | ANALYSIS NOT REQUIRED |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 0 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-01 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-JAN-16 |
|--------------------|-------------|

---

|                   |   |
|-------------------|---|
| Timepoint-minutes | 0 |
|-------------------|---|

---

|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)**

**Generated On: 20 Jul 2016 11:47:42**

---

|               |   |
|---------------|---|
| Urine End Day | 0 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05112520000025 |
|----------------|----------------|

---

|         |     |
|---------|-----|
| Analyte | COT |
|---------|-----|

---

|             |        |
|-------------|--------|
| Sample type | PLASMA |
|-------------|--------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |       |
|------------|-------|
| Lab Status | OTHER |
|------------|-------|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | ANALYSIS NOT REQUIRED |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 0 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-10 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-JAN-16 |
|--------------------|-------------|

---

|                   |   |
|-------------------|---|
| Timepoint-minutes | 0 |
|-------------------|---|

---

|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)**

**Generated On: 20 Jul 2016 11:47:42**

---

|               |   |
|---------------|---|
| Urine End Day | 0 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05112520000025 |
|----------------|----------------|

---

|         |       |
|---------|-------|
| Analyte | THCOT |
|---------|-------|

---

|             |        |
|-------------|--------|
| Sample type | PLASMA |
|-------------|--------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |       |
|------------|-------|
| Lab Status | OTHER |
|------------|-------|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | ANALYSIS NOT REQUIRED |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 0 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-10 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-JAN-16 |
|--------------------|-------------|

---

|                   |   |
|-------------------|---|
| Timepoint-minutes | 0 |
|-------------------|---|

---

|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)**

**Generated On: 20 Jul 2016 11:47:42**

---

|               |   |
|---------------|---|
| Urine End Day | 0 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Date of Visit**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:51**

**Generated On: 20 Jul 2016 11:47:42**

---

Date of Visit

17 JAN 2014  
DD/MMM/YYYY

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Vital Signs**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:51**

**Generated On: 20 Jul 2016 11:47:42**

---

Were Vitals Signs assessed?

Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

Has the subject smoked within 15 minutes prior to  
assessment

No ☒

---

Time of assessment

10:28  
hour:min 24-hour clock

---

Pulse rate

79  
beats per minute

---

Respiratory rate

14  
breaths per minute

---

Blood Pressure (systolic)

98  
mmHg

---

Blood Pressure (diastolic)

66  
mmHg

---

Vital Signs Position of Subject

Supine ☒

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Plasma Nicotine Sample**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:51**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 17 JAN 2014 |
|---------------------|-------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 20:46 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Plasma Cotinine Sample**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:51**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 17 JAN 2014 |
|---------------------|-------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 20:46 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: CoHb Blood Sample**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:51**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 17 JAN 2014 |
|---------------------|-------------|

---

|           |  |
|-----------|--|
| Timepoint | 20:00 - 21:30 <input checked="" type="radio"/> |
|-----------|--|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 20:46 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: CO Breath Test (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:52**

**Generated On: 20 Jul 2016 11:47:42**

---

|                     |       |
|---------------------|-------|
| Assessment not done | False |
|---------------------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                |   |
|----------------|---|
| Scheduled Time | Within 15 min prior to smoking <input checked="" type="radio"/> |
|----------------|---|

---

|   |       |
|---|-------|
| Actual Time of Assessment<br>hour:min 24-hour clock | 07:47 |
|---|-------|

---

|             |    |
|-------------|----|
| Result(ppm) | 10 |
|-------------|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: CO Breath Test (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:52**

**Generated On: 20 Jul 2016 11:47:42**

---

|                     |       |
|---------------------|-------|
| Assessment not done | False |
|---------------------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                |               |                                  |
|----------------|---------------|----------------------------------|
| Scheduled Time | 12:00 - 13:30 | <input checked="" type="radio"/> |
|----------------|---------------|----------------------------------|

---

|   |       |
|---|-------|
| Actual Time of Assessment<br>hour:min 24-hour clock | 12:13 |
|---|-------|

---

|             |   |
|-------------|---|
| Result(ppm) | 6 |
|-------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: CO Breath Test (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:52**

**Generated On: 20 Jul 2016 11:47:42**

---

|                     |       |
|---------------------|-------|
| Assessment not done | False |
|---------------------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                |  |
|----------------|--|
| Scheduled Time | 16:00 - 17:30 <input checked="" type="radio"/> |
|----------------|--|

---

|   |       |
|---|-------|
| Actual Time of Assessment<br>hour:min 24-hour clock | 16:23 |
|---|-------|

---

|             |   |
|-------------|---|
| Result(ppm) | 5 |
|-------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: CO Breath Test (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:52**

**Generated On: 20 Jul 2016 11:47:42**

---

|                     |       |
|---------------------|-------|
| Assessment not done | False |
|---------------------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                |  |
|----------------|--|
| Scheduled Time | 20:00 - 21:30 <input checked="" type="radio"/> |
|----------------|--|

---

|   |       |
|---|-------|
| Actual Time of Assessment<br>hour:min 24-hour clock | 20:30 |
|---|-------|

---

|             |   |
|-------------|---|
| Result(ppm) | 7 |
|-------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: 24 hour urine collections**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:51**

**Generated On: 20 Jul 2016 11:47:42**

---

|            |                        |
|------------|------------------------|
| Start Time | 06:10                  |
|            | hour:min 24-hour clock |

---

|          |             |
|----------|-------------|
| End Date | 18 JAN 2014 |
|          | DD/MMM/YYYY |

---

|          |                        |
|----------|------------------------|
| End Time | 06:07                  |
|          | hour:min 24-hour clock |

---

|        |      |
|--------|------|
| Volume | 1182 |
|        | mL   |

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Sample Urine Collection**

**Generated On: 20 Jul 2016 11:47:42**

---

Were samples for 24h collected?

Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

How many primary tubes were collected?

10

---

How many back up tubes were collected?

12

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:52**

**Generated On: 20 Jul 2016 11:47:42**

---

Date of Birth

(b) (6)

---

Date of assessment  
DD/MMM/YYYY

2014 JAN 17  
DD/MMM/YYYY

---

Time of assessment

06:49  
hour:min 24-hour clock

---

Assessment Status

Completed ☒

---

Please indicate for each of the items below, how you have been feeling over the past 24 hours

---

How have you been feeling over the past 24 hours?

None ☐

1. Angry, irritable, frustrated

---

How have you been feeling over the past 24 hours?

None ☐

2. Anxious, nervous

---

How have you been feeling over the past 24 hours?

None ☐

3. Depressed Mood, sad

---

How have you been feeling over the past 24 hours?

Moderate ☐

4. Desire or craving to smoke

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:52**

**Generated On: 20 Jul 2016 11:47:42**

---

How have you been feeling over the past 24 hours? None ☐

5. Difficulty concentrating

---

How have you been feeling over the past 24 hours? Slight ☐

6. Increased appetite, hungry, weight gain

---

How have you been feeling over the past 24 hours? Slight ☐

7. Insomnia, sleep problems, awakening at night

---

How have you been feeling over the past 24 hours? Slight ☐

8. Restless

---

How have you been feeling over the past 24 hours? None ☐

9. Impatient

---

How have you been feeling over the past 24 hours? Slight ☐

10. Constipation

---

How have you been feeling over the past 24 hours? None ☐

11. Dizziness

---

How have you been feeling over the past 24 hours? None ☐

12. Coughing

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:52**

**Generated On: 20 Jul 2016 11:47:42**

---

How have you been feeling over the past 24 hours?

None ☐

13. Dreaming or nightmares

---

How have you been feeling over the past 24 hours?

None ☐

14. Nausea

---

How have you been feeling over the past 24 hours?

None ☐

15. Sore Throat

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Cough Assessment**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:52**

**Generated On: 20 Jul 2016 11:47:42**

---

|               |         |
|---------------|---------|
| Date of Birth | (b) (6) |
|---------------|---------|

---

---

|                                   |                            |
|-----------------------------------|----------------------------|
| Date of assessment<br>DD/MMM/YYYY | 2014 JAN 17<br>DD/MMM/YYYY |
|-----------------------------------|----------------------------|

---

---

|                    |                                 |
|--------------------|---------------------------------|
| Time of assessment | 06:47<br>hour:min 24-hour clock |
|--------------------|---------------------------------|

---

---

|                   |                                 |
|-------------------|---------------------------------|
| Assessment Status | Completed <input type="radio"/> |
|-------------------|---------------------------------|

---

---

|   |                          |
|---|--------------------------|
| Have you experienced a regular need to cough e.g.<br>coughing several times in the last 24 hrs? | No <input type="radio"/> |
|---|--------------------------|

---

If YES, please answer the following questions:

---

---

|   |    |
|---|----|
| First Question: Cough Impact Scale<br>How much is your cough bothering you? | -9 |
|---|----|

---

---

|   |                                      |
|---|--------------------------------------|
| Second Question: Cough Intensity Scale:<br>How intense is your cough? | Not Applicable <input type="radio"/> |
|---|--------------------------------------|

---

---

|   |                                      |
|---|--------------------------------------|
| Third Question: Cough Frequency Scale:<br>How frequently do you normally have to cough each<br>day? | Not Applicable <input type="radio"/> |
|---|--------------------------------------|

---

---

|   |                                      |
|---|--------------------------------------|
| Fourth Question: Sputum Production<br>To what extent do you produce sputum when coughing? | Not Applicable <input type="radio"/> |
|---|--------------------------------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Lab\_BU\_COHB (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:53**

**Generated On: 20 Jul 2016 11:47:42**

|                               |                       |
|-------------------------------|-----------------------|
| Sample Barcode                | 05115150000100        |
| Analyte                       | CARBOXYHEMOGLOBIN     |
| Sample type                   | BLOOD                 |
| Result                        | .                     |
| Result Unit                   | %                     |
| Lab Status                    | OTHER                 |
| Sample comment                | ANALYSIS NOT REQUIRED |
| Detection method              | SPECTROPHOTOMETRIC    |
| Lower limit of quantification | 0.500                 |
| Planned time point (Hour)     | 20                    |
| Day of Visit                  | 1                     |
| Celerion Study Number         | AA99128-16            |
| Date of Collection            | 2014-JAN-17           |
| Timepoint-minutes             |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Lab\_BU\_COHB (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:53**

**Generated On: 20 Jul 2016 11:47:42**

---

Start Day (24 hour urine only) \_\_\_\_\_

---

End Day (24 hour Urine Only) \_\_\_\_\_

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:52**

**Generated On: 20 Jul 2016 11:47:42**

|  |                                 |
|--|---------------------------------|
| Date of Birth  | (b) (6)                         |
| Date of assessment<br>DD/MMM/YYYY                        | 2014 JAN 17<br>DD/MMM/YYYY      |
| Time of assessment                                       | 20:27<br>hour:min 24-hour clock |
| Assessment Status  | Completed                       |
| 1. Was smoking satisfying?                               | Moderately                      |
| 2. Did cigarettes taste good?                            | Moderately                      |
| 3. Did you enjoy the sensation in your throat and chest? | Little                          |
| 4. Did smoking calm you down?                            | Moderately                      |
| 5. Did smoking make you feel more awake?                 | Moderately                      |
| 6. Did smoking make you feel less irritable?             | Little                          |
| 7. Did smoking help you concentrate?                     | Not at all                      |
| 8. Did smoking reduce your hunger for food?              | Very little                     |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:52**

**Generated On: 20 Jul 2016 11:47:42**

---

9. Did smoking make you dizzy? Little ☐

---

10. Did smoking make you nauseous? Not at all ☐

---

11. Did smoking immediately relieve your craving for a  
cigarette? Moderately ☐

---

12. Did you enjoy smoking? Moderately ☐

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Questionnaire on smoking urges (QSU)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:52**

**Generated On: 20 Jul 2016 11:47:42**

---

|      |     |
|------|-----|
| Type | QSU |
|------|-----|

---

|               |         |
|---------------|---------|
| Date of Birth | (b) (6) |
|---------------|---------|

---

|                    |             |
|--------------------|-------------|
| Date of assessment | 2014 JAN 17 |
|--------------------|-------------|

DD/MMM/YYYY

---

|                    |       |
|--------------------|-------|
| Time of assessment | 20:25 |
|--------------------|-------|

hour:min 24-hour clock

---

|                   |                                 |
|-------------------|---------------------------------|
| Assessment Status | Completed <input type="radio"/> |
|-------------------|---------------------------------|

---

|  |  |
|--|--|
| 1. I have a desire for a cigarette right now | Do not agree or disagree <input type="radio"/> |
|--|--|

---

|   |  |
|---|--|
| 2. Nothing would be better than smoking a cigarette right now | Do not agree or disagree <input type="radio"/> |
|---|--|

---

|   |  |
|---|--|
| 3. If it were possible I would probably smoke now | Do not agree or disagree <input type="radio"/> |
|---|--|

---

|   |                                |
|---|--------------------------------|
| 4. I could control things better right now if I could smoke | Disagree <input type="radio"/> |
|---|--------------------------------|

---

|  |  |
|--|--|
| 5. All I want right now is a cigarette | Do not agree or disagree <input type="radio"/> |
|--|--|

---

|                                   |   |
|-----------------------------------|---|
| 6. I have an urge for a cigarette | Somewhat disagree <input type="radio"/> |
|-----------------------------------|---|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (CEMA, HPMa, HBMA)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:53**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:53**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112450000092        |
| Analyte                   | HPMA                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 1                     |
| Celerion Study Number     | AA99128-03            |
| Date of Collection        | 2014-JAN-17           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 1                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:53**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

---

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:53**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112450000092        |
| Analyte                   | CEMA                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 1                     |
| Celerion Study Number     | AA99128-03            |
| Date of Collection        | 2014-JAN-17           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 1                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:53**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

---

2



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:53**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112450000092        |
| Analyte                   | HBMA                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 1                     |
| Celerion Study Number     | AA99128-03            |
| Date of Collection        | 2014-JAN-17           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 1                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:53**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

---

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (NNN, NNAL)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:52**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (NNN, NNAL) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:52**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112460000092        |
| Analyte                   | NNAL                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | PG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 1                     |
| Celerion Study Number     | AA99128-04            |
| Date of Collection        | 2014-JAN-17           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 1                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (NNN, NNAL) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:52**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

---

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (NNN, NNAL) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:52**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112460000092        |
| Analyte                   | NNN                   |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | PG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 1                     |
| Celerion Study Number     | AA99128-04            |
| Date of Collection        | 2014-JAN-17           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 1                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (NNN, NNAL) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:52**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

2

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (HEMA)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:52**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (HEMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:52**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112470000092        |
| Analyte                   | HEMA                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 1                     |
| Celerion Study Number     | AA99128-05            |
| Date of Collection        | 2014-JAN-17           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 1                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (HEMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:52**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

---

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:53**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:53**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112480000059        |
| Analyte                   | COT                   |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 1                     |
| Celerion Study Number     | AA99128-06            |
| Date of Collection        | 2014-JAN-18           |
| Timepoint-minutes         |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:53**

**Generated On: 20 Jul 2016 11:47:42**

---

|                 |   |
|-----------------|---|
| Urine Start Day | 1 |
|-----------------|---|

---

|               |   |
|---------------|---|
| Urine End Day | 2 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:53**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112480000059        |
| Analyte                   | COT-GLUC              |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 1                     |
| Celerion Study Number     | AA99128-06            |
| Date of Collection        | 2014-JAN-18           |
| Timepoint-minutes         |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:53**

**Generated On: 20 Jul 2016 11:47:42**

---

|                 |   |
|-----------------|---|
| Urine Start Day | 1 |
|-----------------|---|

---

|               |   |
|---------------|---|
| Urine End Day | 2 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:53**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112480000059        |
| Analyte                   | NIC                   |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 1                     |
| Celerion Study Number     | AA99128-06            |
| Date of Collection        | 2014-JAN-18           |
| Timepoint-minutes         |                       |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:53**

**Generated On: 20 Jul 2016 11:47:42**

---

|                 |   |
|-----------------|---|
| Urine Start Day | 1 |
|-----------------|---|

---

|               |   |
|---------------|---|
| Urine End Day | 2 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:53**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112480000059        |
| Analyte                   | NIC-GLUC              |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 1                     |
| Celerion Study Number     | AA99128-06            |
| Date of Collection        | 2014-JAN-18           |
| Timepoint-minutes         |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:53**

**Generated On: 20 Jul 2016 11:47:42**

---

|                 |   |
|-----------------|---|
| Urine Start Day | 1 |
|-----------------|---|

---

|               |   |
|---------------|---|
| Urine End Day | 2 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:53**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112480000059        |
| Analyte                   | THCOT                 |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 1                     |
| Celerion Study Number     | AA99128-06            |
| Date of Collection        | 2014-JAN-18           |
| Timepoint-minutes         |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:53**

**Generated On: 20 Jul 2016 11:47:42**

---

|                 |   |
|-----------------|---|
| Urine Start Day | 1 |
|-----------------|---|

---

|               |   |
|---------------|---|
| Urine End Day | 2 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:53**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112480000059        |
| Analyte                   | THCOT-GLUC            |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 1                     |
| Celerion Study Number     | AA99128-06            |
| Date of Collection        | 2014-JAN-18           |
| Timepoint-minutes         |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:53**

**Generated On: 20 Jul 2016 11:47:42**

---

|                 |   |
|-----------------|---|
| Urine Start Day | 1 |
|-----------------|---|

---

|               |   |
|---------------|---|
| Urine End Day | 2 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (3-OH BaP)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:54**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (3-OH BaP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:54**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112490000092        |
| Analyte                   | 3-OH BAP              |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | FG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 1                     |
| Celerion Study Number     | AA99128-07            |
| Date of Collection        | 2014-JAN-17           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 1                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (3-OH BaP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:54**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

2

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:54**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:54**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112510000092        |
| Analyte                   | 1-NA                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | PG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 1                     |
| Celerion Study Number     | AA99128-09            |
| Date of Collection        | 2014-JAN-17           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 1                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:54**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

---

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:54**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112510000092        |
| Analyte                   | 2-NA                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | PG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 1                     |
| Celerion Study Number     | AA99128-09            |
| Date of Collection        | 2014-JAN-17           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 1                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:54**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

---

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:54**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112510000092        |
| Analyte                   | 4-ABP                 |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | PG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 1                     |
| Celerion Study Number     | AA99128-09            |
| Date of Collection        | 2014-JAN-17           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 1                     |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:54**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

---

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:54**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112510000092        |
| Analyte                   | O-TOL                 |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | PG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 1                     |
| Celerion Study Number     | AA99128-09            |
| Date of Collection        | 2014-JAN-17           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 1                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:54**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

---

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (1-OHP)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:55**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (1-OHP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:55**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05115190001181        |
| Analyte                   | 1-OHP                 |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | PG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 1                     |
| Celerion Study Number     | AA99598-03            |
| Date of Collection        | 2014-JAN-17           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 1                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (1-OHP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:55**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

---

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (SPMA, SBMA)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:52**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (SPMA, SBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:52**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05115170000092        |
| Analyte                   | SBMA                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 1                     |
| Celerion Study Number     | AA99598-01            |
| Date of Collection        | 2014-JAN-17           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 1                     |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (SPMA, SBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:52**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

---

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (SPMA, SBMA) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:52**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05115170000092        |
| Analyte                   | SPMA                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 1                     |
| Celerion Study Number     | AA99598-01            |
| Date of Collection        | 2014-JAN-17           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 1                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (SPMA, SBMA) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:52**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

2

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (MHBMA)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:53**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (MHBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:53**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05115180000092        |
| Analyte                   | MHBMA                 |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 1                     |
| Celerion Study Number     | AA99598-02            |
| Date of Collection        | 2014-JAN-17           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 1                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (MHBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:53**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

---

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (Creatinine)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:54**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (Creatinine) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:54**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05115160000092        |
| Analyte                   | CREATININE            |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | MG/DL                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | SPECTROPHOTOMETRIC    |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 1                     |
| Celerion Study Number     | AA99128-14            |
| Date of Collection        | 2014-JAN-17           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 1                     |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Urine (Creatinine) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:54**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

---

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Plasma (Nic, Cot, tHCot)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:53**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

PLASMA

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:53**

**Generated On: 20 Jul 2016 11:47:42**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05112430000097 |
|----------------|----------------|

---

|         |     |
|---------|-----|
| Analyte | COT |
|---------|-----|

---

|             |        |
|-------------|--------|
| Sample type | PLASMA |
|-------------|--------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |       |
|------------|-------|
| Lab Status | OTHER |
|------------|-------|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | ANALYSIS NOT REQUIRED |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 1 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-01 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-JAN-17 |
|--------------------|-------------|

---

|                   |   |
|-------------------|---|
| Timepoint-minutes | 0 |
|-------------------|---|

---

|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:53**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:53**

**Generated On: 20 Jul 2016 11:47:42**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05112430000097 |
|----------------|----------------|

---

|         |     |
|---------|-----|
| Analyte | NIC |
|---------|-----|

---

|             |        |
|-------------|--------|
| Sample type | PLASMA |
|-------------|--------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |       |
|------------|-------|
| Lab Status | OTHER |
|------------|-------|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | ANALYSIS NOT REQUIRED |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 1 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-01 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-JAN-17 |
|--------------------|-------------|

---

|                   |   |
|-------------------|---|
| Timepoint-minutes | 0 |
|-------------------|---|

---

|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

---

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 1**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:53**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Date of Visit**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:55**

**Generated On: 20 Jul 2016 11:47:42**

---

Date of Visit

18 JAN 2014  
DD/MMM/YYYY

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Vital Signs**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:55**

**Generated On: 20 Jul 2016 11:47:42**

---

Were Vitals Signs assessed?

Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

Has the subject smoked within 15 minutes prior to  
assessment

No ☒

---

Time of assessment

10:16  
hour:min 24-hour clock

---

Pulse rate

75  
beats per minute

---

Respiratory rate

16  
breaths per minute

---

Blood Pressure (systolic)

93  
mmHg

---

Blood Pressure (diastolic)

59  
mmHg

---

Vital Signs Position of Subject

Supine ☒

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Plasma Nicotine Sample**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:55**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 18 JAN 2014 |
|---------------------|-------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 20:36 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Plasma Cotinine Sample**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:55**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 18 JAN 2014 |
|---------------------|-------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 20:36 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: CoHb Blood Sample**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:55**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 18 JAN 2014 |
|---------------------|-------------|

---

|           |  |
|-----------|--|
| Timepoint | 20:00 - 21:30 <input checked="" type="radio"/> |
|-----------|--|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 20:36 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: CO Breath Test (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:55**

**Generated On: 20 Jul 2016 11:47:42**

---

|                     |       |
|---------------------|-------|
| Assessment not done | False |
|---------------------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                |   |
|----------------|---|
| Scheduled Time | Within 15 min prior to smoking <input checked="" type="radio"/> |
|----------------|---|

---

|   |       |
|---|-------|
| Actual Time of Assessment<br>hour:min 24-hour clock | 07:01 |
|---|-------|

---

|             |   |
|-------------|---|
| Result(ppm) | 2 |
|-------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: CO Breath Test (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:55**

**Generated On: 20 Jul 2016 11:47:42**

---

|                     |       |
|---------------------|-------|
| Assessment not done | False |
|---------------------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                |   |
|----------------|---|
| Scheduled Time | 12:00 - 13:30  |
|----------------|---|

---

|   |       |
|---|-------|
| Actual Time of Assessment<br>hour:min 24-hour clock | 12:16 |
|---|-------|

---

|             |   |
|-------------|---|
| Result(ppm) | 1 |
|-------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: CO Breath Test (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:55**

**Generated On: 20 Jul 2016 11:47:42**

---

|                     |       |
|---------------------|-------|
| Assessment not done | False |
|---------------------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                |  |
|----------------|--|
| Scheduled Time | 16:00 - 17:30 <input checked="" type="radio"/> |
|----------------|--|

---

|   |       |
|---|-------|
| Actual Time of Assessment<br>hour:min 24-hour clock | 16:08 |
|---|-------|

---

|             |   |
|-------------|---|
| Result(ppm) | 2 |
|-------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: CO Breath Test (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:55**

**Generated On: 20 Jul 2016 11:47:42**

---

|                     |       |
|---------------------|-------|
| Assessment not done | False |
|---------------------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                |  |
|----------------|--|
| Scheduled Time | 20:00 - 21:30 <input checked="" type="radio"/> |
|----------------|--|

---

|   |       |
|---|-------|
| Actual Time of Assessment<br>hour:min 24-hour clock | 20:27 |
|---|-------|

---

|             |   |
|-------------|---|
| Result(ppm) | 4 |
|-------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: 24 hour urine collections**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:55**

**Generated On: 20 Jul 2016 11:47:42**

---

|            |                        |
|------------|------------------------|
| Start Time | 06:07                  |
|            | hour:min 24-hour clock |

---

|          |             |
|----------|-------------|
| End Date | 19 JAN 2014 |
|          | DD/MMM/YYYY |

---

|          |                        |
|----------|------------------------|
| End Time | 06:22                  |
|          | hour:min 24-hour clock |

---

|        |      |
|--------|------|
| Volume | 1123 |
|        | mL   |

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Sample Urine Collection**

**Generated On: 20 Jul 2016 11:47:42**

---

Were samples for 24h collected?

Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

How many primary tubes were collected?

10

---

How many back up tubes were collected?

12

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:56**

**Generated On: 20 Jul 2016 11:47:42**

---

|               |         |
|---------------|---------|
| Date of Birth | (b) (6) |
|---------------|---------|

---

|                                   |                            |
|-----------------------------------|----------------------------|
| Date of assessment<br>DD/MMM/YYYY | 2014 JAN 18<br>DD/MMM/YYYY |
|-----------------------------------|----------------------------|

---

|                    |                                 |
|--------------------|---------------------------------|
| Time of assessment | 06:16<br>hour:min 24-hour clock |
|--------------------|---------------------------------|

---

|                   |  |
|-------------------|--|
| Assessment Status | Completed <input checked="" type="radio"/> |
|-------------------|--|

---

Please indicate for each of the items below, how you have been feeling over the past 24 hours

---

|   |                            |
|---|----------------------------|
| How have you been feeling over the past 24 hours? | None <input type="radio"/> |
|---|----------------------------|

1. Angry, irritable, frustrated

---

|   |                            |
|---|----------------------------|
| How have you been feeling over the past 24 hours? | None <input type="radio"/> |
|---|----------------------------|

2. Anxious, nervous

---

|   |                            |
|---|----------------------------|
| How have you been feeling over the past 24 hours? | None <input type="radio"/> |
|---|----------------------------|

3. Depressed Mood, sad

---

|   |                                |
|---|--------------------------------|
| How have you been feeling over the past 24 hours? | Moderate <input type="radio"/> |
|---|--------------------------------|

4. Desire or craving to smoke

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Day 2**

**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:56**

**Generated On: 20 Jul 2016 11:47:42**

---

How have you been feeling over the past 24 hours? None ☐

5. Difficulty concentrating

---

How have you been feeling over the past 24 hours? Mild ☐

6. Increased appetite, hungry, weight gain

---

How have you been feeling over the past 24 hours? None ☐

7. Insomnia, sleep problems, awakening at night

---

How have you been feeling over the past 24 hours? Mild ☐

8. Restless

---

How have you been feeling over the past 24 hours? None ☐

9. Impatient

---

How have you been feeling over the past 24 hours? Slight ☐

10. Constipation

---

How have you been feeling over the past 24 hours? None ☐

11. Dizziness

---

How have you been feeling over the past 24 hours? None ☐

12. Coughing

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:56**

**Generated On: 20 Jul 2016 11:47:42**

---

How have you been feeling over the past 24 hours?

None ☐

13. Dreaming or nightmares

---

How have you been feeling over the past 24 hours?

None ☐

14. Nausea

---

How have you been feeling over the past 24 hours?

None ☐

15. Sore Throat

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Cough Assessment**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:57**

**Generated On: 20 Jul 2016 11:47:42**

---

|               |         |
|---------------|---------|
| Date of Birth | (b) (6) |
|---------------|---------|

---

---

|                                   |                            |
|-----------------------------------|----------------------------|
| Date of assessment<br>DD/MMM/YYYY | 2014 JAN 18<br>DD/MMM/YYYY |
|-----------------------------------|----------------------------|

---

---

|                    |                                 |
|--------------------|---------------------------------|
| Time of assessment | 06:13<br>hour:min 24-hour clock |
|--------------------|---------------------------------|

---

---

|                   |  |
|-------------------|--|
| Assessment Status | Completed <input checked="" type="radio"/> |
|-------------------|--|

---

---

|   |                                     |
|---|-------------------------------------|
| Have you experienced a regular need to cough e.g.<br>coughing several times in the last 24 hrs? | No <input checked="" type="radio"/> |
|---|-------------------------------------|

---

If YES, please answer the following questions:

---

---

|   |    |
|---|----|
| First Question: Cough Impact Scale<br>How much is your cough bothering you? | -9 |
|---|----|

---

---

|   |   |
|---|---|
| Second Question: Cough Intensity Scale:<br>How intense is your cough? | Not Applicable <input checked="" type="radio"/> |
|---|---|

---

---

|   |   |
|---|---|
| Third Question: Cough Frequency Scale:<br>How frequently do you normally have to cough each<br>day? | Not Applicable <input checked="" type="radio"/> |
|---|---|

---

---

|   |   |
|---|---|
| Fourth Question: Sputum Production<br>To what extent do you produce sputum when coughing? | Not Applicable <input checked="" type="radio"/> |
|---|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Lab\_BU\_COHB (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:57**

**Generated On: 20 Jul 2016 11:47:42**

|                               |                       |
|-------------------------------|-----------------------|
| Sample Barcode                | 05115150000101        |
| Analyte                       | CARBOXYHEMOGLOBIN     |
| Sample type                   | BLOOD                 |
| Result                        | .                     |
| Result Unit                   | %                     |
| Lab Status                    | OTHER                 |
| Sample comment                | ANALYSIS NOT REQUIRED |
| Detection method              | SPECTROPHOTOMETRIC    |
| Lower limit of quantification | 0.500                 |
| Planned time point (Hour)     | 20                    |
| Day of Visit                  | 2                     |
| Celerion Study Number         | AA99128-16            |
| Date of Collection            | 2014-JAN-18           |
| Timepoint-minutes             |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Lab\_BU\_COHB (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:57**

**Generated On: 20 Jul 2016 11:47:42**

---

Start Day (24 hour urine only)

---

End Day (24 hour Urine Only)

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:56**

**Generated On: 20 Jul 2016 11:47:42**

---

Date of Birth

(b) (6)

---

Date of assessment

2014 JAN 18

DD/MMM/YYYY

DD/MMM/YYYY

---

Time of assessment

20:24  
hour:min 24-hour clock

---

Assessment Status

Completed ☒

---

1. Was smoking satisfying?

Moderately ☒

---

2. Did cigarettes taste good?

Moderately ☒

---

3. Did you enjoy the sensation in your throat and chest?

Very little ☒

---

4. Did smoking calm you down?

Moderately ☒

---

5. Did smoking make you feel more awake?

Moderately ☒

---

6. Did smoking make you feel less irritable?

Not at all ☒

---

7. Did smoking help you concentrate?

Not at all ☒

---

8. Did smoking reduce your hunger for food?

Very little ☒



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:56**

**Generated On: 20 Jul 2016 11:47:42**

---

9. Did smoking make you dizzy? Not at all ☐

---

10. Did smoking make you nauseous? Not at all ☐

---

11. Did smoking immediately relieve your craving for a  
cigarette? Moderately ☐

---

12. Did you enjoy smoking? Moderately ☐

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Questionnaire on smoking urges (QSU)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:56**

**Generated On: 20 Jul 2016 11:47:42**

---

|      |     |
|------|-----|
| Type | QSU |
|------|-----|

---

|               |         |
|---------------|---------|
| Date of Birth | (b) (6) |
|---------------|---------|

---

|                    |             |
|--------------------|-------------|
| Date of assessment | 2014 JAN 18 |
|--------------------|-------------|

DD/MMM/YYYY

---

|                    |       |
|--------------------|-------|
| Time of assessment | 20:23 |
|--------------------|-------|

hour:min 24-hour clock

---

|                   |  |
|-------------------|--|
| Assessment Status | Completed <input checked="" type="radio"/> |
|-------------------|--|

---

|  |   |
|--|---|
| 1. I have a desire for a cigarette right now | Somewhat agree <input checked="" type="radio"/> |
|--|---|

---

|  |   |
|--|---|
| 2. Nothing would be better than smoking a cigarette<br>right now | Somewhat agree <input checked="" type="radio"/> |
|--|---|

---

|   |  |
|---|--|
| 3. If it were possible I would probably smoke now | Agree <input checked="" type="radio"/> |
|---|--|

---

|   |   |
|---|---|
| 4. I could control things better right now if I could smoke | Disagree <input checked="" type="radio"/> |
|---|---|

---

|  |   |
|--|---|
| 5. All I want right now is a cigarette | Do not agree or disagree <input checked="" type="radio"/> |
|--|---|

---

|                                   |   |
|-----------------------------------|---|
| 6. I have an urge for a cigarette | Somewhat agree <input checked="" type="radio"/> |
|-----------------------------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Questionnaire on smoking urges (QSU)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:56**

**Generated On: 20 Jul 2016 11:47:42**

---

7. A cigarette would taste good now Somewhat agree ☐

---

8. I would do almost anything for a cigarette now Do not agree or disagree ☐

---

9. Smoking would make me less depressed Strongly disagree ☐

---

10. I am going to smoke as soon as possible Agree ☐

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (CEMA, HPMa, HBMA)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:57**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:57**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112450000093        |
| Analyte                   | HPMA                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 2                     |
| Celerion Study Number     | AA99128-03            |
| Date of Collection        | 2014-JAN-18           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 2                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:57**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

---

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:57**

**Generated On: 20 Jul 2016 11:47:42**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05112450000093 |
|----------------|----------------|

---

|         |      |
|---------|------|
| Analyte | CEMA |
|---------|------|

---

|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |       |
|------------|-------|
| Lab Status | OTHER |
|------------|-------|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | ANALYSIS NOT REQUIRED |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 2 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-03 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-JAN-18 |
|--------------------|-------------|

---

|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

---

|                 |   |
|-----------------|---|
| Urine Start Day | 2 |
|-----------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:57**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

3

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:57**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112450000093        |
| Analyte                   | HBMA                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 2                     |
| Celerion Study Number     | AA99128-03            |
| Date of Collection        | 2014-JAN-18           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 2                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:57**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

3

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (NNN, NNAL)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:57**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (NNN, NNAL) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:57**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112460000093        |
| Analyte                   | NNAL                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | PG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 2                     |
| Celerion Study Number     | AA99128-04            |
| Date of Collection        | 2014-JAN-18           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 2                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (NNN, NNAL) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:57**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

3

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (NNN, NNAL) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:57**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112460000093        |
| Analyte                   | NNN                   |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | PG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 2                     |
| Celerion Study Number     | AA99128-04            |
| Date of Collection        | 2014-JAN-18           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 2                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (NNN, NNAL) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:57**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

3

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (HEMA)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:57**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (HEMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:57**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112470000093        |
| Analyte                   | HEMA                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 2                     |
| Celerion Study Number     | AA99128-05            |
| Date of Collection        | 2014-JAN-18           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 2                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (HEMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:57**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

3

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:57**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:57**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112480000060        |
| Analyte                   | COT                   |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 2                     |
| Celerion Study Number     | AA99128-06            |
| Date of Collection        | 2014-JAN-19           |
| Timepoint-minutes         |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:57**

**Generated On: 20 Jul 2016 11:47:42**

---

|                 |   |
|-----------------|---|
| Urine Start Day | 2 |
|-----------------|---|

---

|               |   |
|---------------|---|
| Urine End Day | 3 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:57**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112480000060        |
| Analyte                   | COT-GLUC              |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 2                     |
| Celerion Study Number     | AA99128-06            |
| Date of Collection        | 2014-JAN-19           |
| Timepoint-minutes         |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:57**

**Generated On: 20 Jul 2016 11:47:42**

---

|                 |   |
|-----------------|---|
| Urine Start Day | 2 |
|-----------------|---|

---

|               |   |
|---------------|---|
| Urine End Day | 3 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:57**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112480000060        |
| Analyte                   | NIC                   |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 2                     |
| Celerion Study Number     | AA99128-06            |
| Date of Collection        | 2014-JAN-19           |
| Timepoint-minutes         |                       |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:57**

**Generated On: 20 Jul 2016 11:47:42**

---

|                 |   |
|-----------------|---|
| Urine Start Day | 2 |
|-----------------|---|

---

|               |   |
|---------------|---|
| Urine End Day | 3 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:57**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112480000060        |
| Analyte                   | NIC-GLUC              |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 2                     |
| Celerion Study Number     | AA99128-06            |
| Date of Collection        | 2014-JAN-19           |
| Timepoint-minutes         |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:57**

**Generated On: 20 Jul 2016 11:47:42**

---

|                 |   |
|-----------------|---|
| Urine Start Day | 2 |
|-----------------|---|

---

|               |   |
|---------------|---|
| Urine End Day | 3 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:57**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112480000060        |
| Analyte                   | THCOT                 |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 2                     |
| Celerion Study Number     | AA99128-06            |
| Date of Collection        | 2014-JAN-19           |
| Timepoint-minutes         |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:57**

**Generated On: 20 Jul 2016 11:47:42**

---

|                 |   |
|-----------------|---|
| Urine Start Day | 2 |
|-----------------|---|

---

|               |   |
|---------------|---|
| Urine End Day | 3 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:57**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112480000060        |
| Analyte                   | THCOT-GLUC            |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 2                     |
| Celerion Study Number     | AA99128-06            |
| Date of Collection        | 2014-JAN-19           |
| Timepoint-minutes         |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:57**

**Generated On: 20 Jul 2016 11:47:42**

---

|                 |   |
|-----------------|---|
| Urine Start Day | 2 |
|-----------------|---|

---

|               |   |
|---------------|---|
| Urine End Day | 3 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (3-OH BaP)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:58**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (3-OH BaP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:58**

**Generated On: 20 Jul 2016 11:47:42**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05112490000093 |
|----------------|----------------|

---

|         |          |
|---------|----------|
| Analyte | 3-OH BAP |
|---------|----------|

---

|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | FG/ML |
|-------------|-------|

---

|            |       |
|------------|-------|
| Lab Status | OTHER |
|------------|-------|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | ANALYSIS NOT REQUIRED |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 2 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-07 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-JAN-18 |
|--------------------|-------------|

---

|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

---

|                 |   |
|-----------------|---|
| Urine Start Day | 2 |
|-----------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (3-OH BaP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:58**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

3

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:58**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:58**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112510000093        |
| Analyte                   | 1-NA                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | PG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 2                     |
| Celerion Study Number     | AA99128-09            |
| Date of Collection        | 2014-JAN-18           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 2                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:58**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

---

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:58**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112510000093        |
| Analyte                   | 2-NA                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | PG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 2                     |
| Celerion Study Number     | AA99128-09            |
| Date of Collection        | 2014-JAN-18           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 2                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:58**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

---

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:58**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112510000093        |
| Analyte                   | 4-ABP                 |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | PG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 2                     |
| Celerion Study Number     | AA99128-09            |
| Date of Collection        | 2014-JAN-18           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 2                     |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:58**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

3

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:58**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112510000093        |
| Analyte                   | O-TOL                 |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | PG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 2                     |
| Celerion Study Number     | AA99128-09            |
| Date of Collection        | 2014-JAN-18           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 2                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:58**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

---

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (1-OHP)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:58**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (1-OHP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:58**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05115190001182        |
| Analyte                   | 1-OHP                 |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | PG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 2                     |
| Celerion Study Number     | AA99598-03            |
| Date of Collection        | 2014-JAN-18           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 2                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (1-OHP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:58**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

---

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (SPMA, SBMA)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:57**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (SPMA, SBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:57**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05115170000093        |
| Analyte                   | SBMA                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 2                     |
| Celerion Study Number     | AA99598-01            |
| Date of Collection        | 2014-JAN-18           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 2                     |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (SPMA, SBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:57**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

3

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (SPMA, SBMA) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:57**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05115170000093        |
| Analyte                   | SPMA                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 2                     |
| Celerion Study Number     | AA99598-01            |
| Date of Collection        | 2014-JAN-18           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 2                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (SPMA, SBMA) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:57**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

3

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (MHBMA)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:57**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (MHBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:57**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05115180000093        |
| Analyte                   | MHBMA                 |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 2                     |
| Celerion Study Number     | AA99598-02            |
| Date of Collection        | 2014-JAN-18           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 2                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (MHBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:57**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

3

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (Creatinine)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:58**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (Creatinine) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:58**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05115160000093        |
| Analyte                   | CREATININE            |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | MG/DL                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | SPECTROPHOTOMETRIC    |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 2                     |
| Celerion Study Number     | AA99128-14            |
| Date of Collection        | 2014-JAN-18           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 2                     |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Urine (Creatinine) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:58**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

3

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Plasma (Nic, Cot, tHCot)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:57**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

PLASMA

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:57**

**Generated On: 20 Jul 2016 11:47:42**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05112430000098 |
|----------------|----------------|

---

|         |     |
|---------|-----|
| Analyte | COT |
|---------|-----|

---

|             |        |
|-------------|--------|
| Sample type | PLASMA |
|-------------|--------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |       |
|------------|-------|
| Lab Status | OTHER |
|------------|-------|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | ANALYSIS NOT REQUIRED |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 2 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-01 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-JAN-18 |
|--------------------|-------------|

---

|                   |   |
|-------------------|---|
| Timepoint-minutes | 0 |
|-------------------|---|

---

|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:57**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

2

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:57**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112430000098        |
| Analyte                   | NIC                   |
| Sample type               | PLASMA                |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 2                     |
| Celerion Study Number     | AA99128-01            |
| Date of Collection        | 2014-JAN-18           |
| Timepoint-minutes         | 0                     |
| Urine Start Day           |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 2**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:57**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

2

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Date of Visit**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:58**

**Generated On: 20 Jul 2016 11:47:42**

---

Date of Visit

19 JAN 2014  
DD/MMM/YYYY

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Vital Signs**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:58**

**Generated On: 20 Jul 2016 11:47:42**

---

Were Vitals Signs assessed? Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

Has the subject smoked within 15 minutes prior to assessment No ☒

---

Time of assessment 09:50  
hour:min 24-hour clock

---

Pulse rate 83  
beats per minute

---

Respiratory rate 16  
breaths per minute

---

Blood Pressure (systolic) 107  
mmHg

---

Blood Pressure (diastolic) 71  
mmHg

---

Vital Signs Position of Subject Supine ☒



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Plasma Nicotine Sample**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:58**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 19 JAN 2014 |
|---------------------|-------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 20:50 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Plasma Cotinine Sample**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:58**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 19 JAN 2014 |
|---------------------|-------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 20:50 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: CoHb Blood Sample**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:58**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 19 JAN 2014 |
|---------------------|-------------|

---

|           |  |
|-----------|--|
| Timepoint | 20:00 - 21:30 <input checked="" type="radio"/> |
|-----------|--|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 20:50 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: CO Breath Test (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:58**

**Generated On: 20 Jul 2016 11:47:42**

---

|                     |       |
|---------------------|-------|
| Assessment not done | False |
|---------------------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                |   |
|----------------|---|
| Scheduled Time | Within 15 min prior to smoking <input checked="" type="radio"/> |
|----------------|---|

---

|   |       |
|---|-------|
| Actual Time of Assessment<br>hour:min 24-hour clock | 06:51 |
|---|-------|

---

|             |   |
|-------------|---|
| Result(ppm) | 2 |
|-------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: CO Breath Test (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:58**

**Generated On: 20 Jul 2016 11:47:42**

---

|                     |       |
|---------------------|-------|
| Assessment not done | False |
|---------------------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                |   |
|----------------|---|
| Scheduled Time | 12:00 - 13:30  |
|----------------|---|

---

|   |       |
|---|-------|
| Actual Time of Assessment<br>hour:min 24-hour clock | 12:07 |
|---|-------|

---

|             |   |
|-------------|---|
| Result(ppm) | 2 |
|-------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: CO Breath Test (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:58**

**Generated On: 20 Jul 2016 11:47:42**

---

|                     |       |
|---------------------|-------|
| Assessment not done | False |
|---------------------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                |  |
|----------------|--|
| Scheduled Time | 16:00 - 17:30 <input checked="" type="radio"/> |
|----------------|--|

---

|   |       |
|---|-------|
| Actual Time of Assessment<br>hour:min 24-hour clock | 16:51 |
|---|-------|

---

|             |   |
|-------------|---|
| Result(ppm) | 2 |
|-------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: CO Breath Test (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:58**

**Generated On: 20 Jul 2016 11:47:42**

---

|                     |       |
|---------------------|-------|
| Assessment not done | False |
|---------------------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                |  |
|----------------|--|
| Scheduled Time | 20:00 - 21:30 <input checked="" type="radio"/> |
|----------------|--|

---

|   |       |
|---|-------|
| Actual Time of Assessment<br>hour:min 24-hour clock | 20:37 |
|---|-------|

---

|             |   |
|-------------|---|
| Result(ppm) | 3 |
|-------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: 24 hour urine collections**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:58**

**Generated On: 20 Jul 2016 11:47:42**

---

|            |                        |
|------------|------------------------|
| Start Time | 06:22                  |
|            | hour:min 24-hour clock |

---

|          |             |
|----------|-------------|
| End Date | 20 JAN 2014 |
|          | DD/MMM/YYYY |

---

|          |                        |
|----------|------------------------|
| End Time | 06:08                  |
|          | hour:min 24-hour clock |

---

|        |     |
|--------|-----|
| Volume | 933 |
|        | mL  |

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Sample Urine Collection**

**Generated On: 20 Jul 2016 11:47:42**

---

Were samples for 24h collected?

Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

How many primary tubes were collected?

10

---

How many back up tubes were collected?

12

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Day 3**

**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:58**

**Generated On: 20 Jul 2016 11:47:42**

---

Date of Birth

(b) (6)

---

Date of assessment  
DD/MMM/YYYY

2014 JAN 19  
DD/MMM/YYYY

---

Time of assessment

06:20  
hour:min 24-hour clock

---

Assessment Status

Completed ☒

---

Please indicate for each of the items below, how you have been feeling over the past 24 hours

---

How have you been feeling over the past 24 hours?

None ☐

1. Angry, irritable, frustrated

---

How have you been feeling over the past 24 hours?

None ☐

2. Anxious, nervous

---

How have you been feeling over the past 24 hours?

None ☐

3. Depressed Mood, sad

---

How have you been feeling over the past 24 hours?

Moderate ☐

4. Desire or craving to smoke

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Day 3**

**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:58**

**Generated On: 20 Jul 2016 11:47:42**

---

How have you been feeling over the past 24 hours? None ☐

5. Difficulty concentrating

---

How have you been feeling over the past 24 hours? Moderate ☐

6. Increased appetite, hungry, weight gain

---

How have you been feeling over the past 24 hours? Slight ☐

7. Insomnia, sleep problems, awakening at night

---

How have you been feeling over the past 24 hours? Slight ☐

8. Restless

---

How have you been feeling over the past 24 hours? None ☐

9. Impatient

---

How have you been feeling over the past 24 hours? Mild ☐

10. Constipation

---

How have you been feeling over the past 24 hours? None ☐

11. Dizziness

---

How have you been feeling over the past 24 hours? None ☐

12. Coughing

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:58**

**Generated On: 20 Jul 2016 11:47:42**

---

How have you been feeling over the past 24 hours?

None ☐

13. Dreaming or nightmares

---

How have you been feeling over the past 24 hours?

None ☐

14. Nausea

---

How have you been feeling over the past 24 hours?

None ☐

15. Sore Throat

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Cough Assessment**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:59**

**Generated On: 20 Jul 2016 11:47:42**

---

Date of Birth

(b) (6)

---

Date of assessment  
DD/MMM/YYYY

2014 JAN 19  
DD/MMM/YYYY

---

Time of assessment

06:18  
hour:min 24-hour clock

---

Assessment Status

Completed ☒

---

Have you experienced a regular need to cough e.g.  
coughing several times in the last 24 hrs?

No ☒

---

If YES, please answer the following questions:

---

First Question: Cough Impact Scale  
How much is your cough bothering you?

-9

---

Second Question: Cough Intensity Scale:  
How intense is your cough?

Not Applicable ☒

---

Third Question: Cough Frequency Scale:  
How frequently do you normally have to cough each  
day?

Not Applicable ☒

---

Fourth Question: Sputum Production  
To what extent do you produce sputum when coughing?

Not Applicable ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Lab\_BU\_COHB (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:59**

**Generated On: 20 Jul 2016 11:47:42**

|                               |                       |
|-------------------------------|-----------------------|
| Sample Barcode                | 05115150000102        |
| Analyte                       | CARBOXYHEMOGLOBIN     |
| Sample type                   | BLOOD                 |
| Result                        | .                     |
| Result Unit                   | %                     |
| Lab Status                    | OTHER                 |
| Sample comment                | ANALYSIS NOT REQUIRED |
| Detection method              | SPECTROPHOTOMETRIC    |
| Lower limit of quantification | 0.500                 |
| Planned time point (Hour)     | 20                    |
| Day of Visit                  | 3                     |
| Celerion Study Number         | AA99128-16            |
| Date of Collection            | 2014-JAN-19           |
| Timepoint-minutes             |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Lab\_BU\_COHB (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:59**

**Generated On: 20 Jul 2016 11:47:42**

---

Start Day (24 hour urine only) \_\_\_\_\_

---

End Day (24 hour Urine Only) \_\_\_\_\_

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:58**

**Generated On: 20 Jul 2016 11:47:42**

---

Date of Birth

(b) (6)

---

Date of assessment

2014 JAN 19

DD/MMM/YYYY

DD/MMM/YYYY

---

Time of assessment

20:08

hour:min 24-hour clock

---

Assessment Status

Completed ☒

---

1. Was smoking satisfying?

Moderately ☒

---

2. Did cigarettes taste good?

Moderately ☒

---

3. Did you enjoy the sensation in your throat and chest?

Little ☒

---

4. Did smoking calm you down?

Moderately ☒

---

5. Did smoking make you feel more awake?

Moderately ☒

---

6. Did smoking make you feel less irritable?

Little ☒

---

7. Did smoking help you concentrate?

Not at all ☒

---

8. Did smoking reduce your hunger for food?

Very little ☒



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:58**

**Generated On: 20 Jul 2016 11:47:42**

---

9. Did smoking make you dizzy? Very little ☐

---

10. Did smoking make you nauseous? Not at all ☐

---

11. Did smoking immediately relieve your craving for a  
cigarette? Moderately ☐

---

12. Did you enjoy smoking? Moderately ☐

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Questionnaire on smoking urges (QSU)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:58**

**Generated On: 20 Jul 2016 11:47:42**

---

|      |     |
|------|-----|
| Type | QSU |
|------|-----|

---

|               |         |
|---------------|---------|
| Date of Birth | (b) (6) |
|---------------|---------|

---

|                    |             |
|--------------------|-------------|
| Date of assessment | 2014 JAN 19 |
|--------------------|-------------|

DD/MMM/YYYY

---

|                    |       |
|--------------------|-------|
| Time of assessment | 20:07 |
|--------------------|-------|

hour:min 24-hour clock

---

|                   |  |
|-------------------|--|
| Assessment Status | Completed <input checked="" type="radio"/> |
|-------------------|--|

---

|  |   |
|--|---|
| 1. I have a desire for a cigarette right now | Strongly agree <input checked="" type="radio"/> |
|--|---|

---

|  |   |
|--|---|
| 2. Nothing would be better than smoking a cigarette<br>right now | Strongly agree <input checked="" type="radio"/> |
|--|---|

---

|   |   |
|---|---|
| 3. If it were possible I would probably smoke now | Strongly agree <input checked="" type="radio"/> |
|---|---|

---

|   |   |
|---|---|
| 4. I could control things better right now if I could smoke | Disagree <input checked="" type="radio"/> |
|---|---|

---

|  |  |
|--|--|
| 5. All I want right now is a cigarette | Agree <input checked="" type="radio"/> |
|--|--|

---

|                                   |   |
|-----------------------------------|---|
| 6. I have an urge for a cigarette | Strongly agree <input checked="" type="radio"/> |
|-----------------------------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Questionnaire on smoking urges (QSU)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:58**

**Generated On: 20 Jul 2016 11:47:42**

---

7. A cigarette would taste good now Strongly agree ☒

---

8. I would do almost anything for a cigarette now Somewhat disagree ☒

---

9. Smoking would make me less depressed Strongly disagree ☒

---

10. I am going to smoke as soon as possible Strongly agree ☒

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (CEMA, HPMa, HBMA)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:59**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:59**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112450000094        |
| Analyte                   | HPMA                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 3                     |
| Celerion Study Number     | AA99128-03            |
| Date of Collection        | 2014-JAN-19           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 3                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (CEMA, HPMa, HBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:59**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

---

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:59**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112450000094        |
| Analyte                   | CEMA                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 3                     |
| Celerion Study Number     | AA99128-03            |
| Date of Collection        | 2014-JAN-19           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 3                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:59**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

---

4



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:59**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112450000094        |
| Analyte                   | HBMA                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 3                     |
| Celerion Study Number     | AA99128-03            |
| Date of Collection        | 2014-JAN-19           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 3                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (CEMA, HPMa, HBMA) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:59**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

---

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (NNN, NNAL)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:59**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (NNN, NNAL) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:59**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112460000094        |
| Analyte                   | NNAL                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | PG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 3                     |
| Celerion Study Number     | AA99128-04            |
| Date of Collection        | 2014-JAN-19           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 3                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (NNN, NNAL) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:59**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

---

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (NNN, NNAL) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:59**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112460000094        |
| Analyte                   | NNN                   |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | PG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 3                     |
| Celerion Study Number     | AA99128-04            |
| Date of Collection        | 2014-JAN-19           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 3                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (NNN, NNAL) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:59**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

---

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (HEMA)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:59**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (HEMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:59**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112470000094        |
| Analyte                   | HEMA                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 3                     |
| Celerion Study Number     | AA99128-05            |
| Date of Collection        | 2014-JAN-19           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 3                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (HEMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:59**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

---

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:00**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:00**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112480000061        |
| Analyte                   | COT                   |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 3                     |
| Celerion Study Number     | AA99128-06            |
| Date of Collection        | 2014-JAN-20           |
| Timepoint-minutes         |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:00**

**Generated On: 20 Jul 2016 11:47:42**

---

|                 |   |
|-----------------|---|
| Urine Start Day | 3 |
|-----------------|---|

---

|               |   |
|---------------|---|
| Urine End Day | 4 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:00**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112480000061        |
| Analyte                   | COT-GLUC              |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 3                     |
| Celerion Study Number     | AA99128-06            |
| Date of Collection        | 2014-JAN-20           |
| Timepoint-minutes         |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:00**

**Generated On: 20 Jul 2016 11:47:42**

---

|                 |   |
|-----------------|---|
| Urine Start Day | 3 |
|-----------------|---|

---

|               |   |
|---------------|---|
| Urine End Day | 4 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:00**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112480000061        |
| Analyte                   | NIC                   |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 3                     |
| Celerion Study Number     | AA99128-06            |
| Date of Collection        | 2014-JAN-20           |
| Timepoint-minutes         |                       |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:00**

**Generated On: 20 Jul 2016 11:47:42**

---

|                 |   |
|-----------------|---|
| Urine Start Day | 3 |
|-----------------|---|

---

|               |   |
|---------------|---|
| Urine End Day | 4 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:00**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112480000061        |
| Analyte                   | NIC-GLUC              |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 3                     |
| Celerion Study Number     | AA99128-06            |
| Date of Collection        | 2014-JAN-20           |
| Timepoint-minutes         |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:00**

**Generated On: 20 Jul 2016 11:47:42**

---

|                 |   |
|-----------------|---|
| Urine Start Day | 3 |
|-----------------|---|

---

|               |   |
|---------------|---|
| Urine End Day | 4 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:00**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112480000061        |
| Analyte                   | THCOT                 |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 3                     |
| Celerion Study Number     | AA99128-06            |
| Date of Collection        | 2014-JAN-20           |
| Timepoint-minutes         |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:00**

**Generated On: 20 Jul 2016 11:47:42**

---

|                 |   |
|-----------------|---|
| Urine Start Day | 3 |
|-----------------|---|

---

|               |   |
|---------------|---|
| Urine End Day | 4 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:00**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112480000061        |
| Analyte                   | THCOT-GLUC            |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 3                     |
| Celerion Study Number     | AA99128-06            |
| Date of Collection        | 2014-JAN-20           |
| Timepoint-minutes         |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:00**

**Generated On: 20 Jul 2016 11:47:42**

---

|                 |   |
|-----------------|---|
| Urine Start Day | 3 |
|-----------------|---|

---

|               |   |
|---------------|---|
| Urine End Day | 4 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (3-OH BaP)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:00**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (3-OH BaP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:00**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112490000094        |
| Analyte                   | 3-OH BAP              |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | FG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 3                     |
| Celerion Study Number     | AA99128-07            |
| Date of Collection        | 2014-JAN-19           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 3                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (3-OH BaP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:00**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

4

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:00**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:00**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112510000094        |
| Analyte                   | 1-NA                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | PG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 3                     |
| Celerion Study Number     | AA99128-09            |
| Date of Collection        | 2014-JAN-19           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 3                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:00**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

---

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:00**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112510000094        |
| Analyte                   | 2-NA                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | PG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 3                     |
| Celerion Study Number     | AA99128-09            |
| Date of Collection        | 2014-JAN-19           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 3                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:00**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

---

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:00**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112510000094        |
| Analyte                   | 4-ABP                 |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | PG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 3                     |
| Celerion Study Number     | AA99128-09            |
| Date of Collection        | 2014-JAN-19           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 3                     |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:00**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

---

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:00**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112510000094        |
| Analyte                   | O-TOL                 |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | PG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 3                     |
| Celerion Study Number     | AA99128-09            |
| Date of Collection        | 2014-JAN-19           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 3                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:00**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

---

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (1-OHP)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:00**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (1-OHP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:00**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05115190001183        |
| Analyte                   | 1-OHP                 |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | PG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 3                     |
| Celerion Study Number     | AA99598-03            |
| Date of Collection        | 2014-JAN-19           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 3                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (1-OHP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:00**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

---

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (SPMA, SBMA)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:59**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (SPMA, SBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:59**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05115170000094        |
| Analyte                   | SBMA                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 3                     |
| Celerion Study Number     | AA99598-01            |
| Date of Collection        | 2014-JAN-19           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 3                     |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (SPMA, SBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:59**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

4

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (SPMA, SBMA) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:59**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05115170000094        |
| Analyte                   | SPMA                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 3                     |
| Celerion Study Number     | AA99598-01            |
| Date of Collection        | 2014-JAN-19           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 3                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (SPMA, SBMA) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:59**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

4

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (MHBMA)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:59**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (MHBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:59**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05115180000094        |
| Analyte                   | MHBMA                 |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 3                     |
| Celerion Study Number     | AA99598-02            |
| Date of Collection        | 2014-JAN-19           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 3                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (MHBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:59**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

---

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (Creatinine)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:00**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (Creatinine) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:00**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05115160000094        |
| Analyte                   | CREATININE            |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | MG/DL                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | SPECTROPHOTOMETRIC    |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 3                     |
| Celerion Study Number     | AA99128-14            |
| Date of Collection        | 2014-JAN-19           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 3                     |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Urine (Creatinine) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:00**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

---

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Plasma (Nic, Cot, tHCot)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:59**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

PLASMA

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:59**

**Generated On: 20 Jul 2016 11:47:42**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05112430000099 |
|----------------|----------------|

---

|         |     |
|---------|-----|
| Analyte | COT |
|---------|-----|

---

|             |        |
|-------------|--------|
| Sample type | PLASMA |
|-------------|--------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |       |
|------------|-------|
| Lab Status | OTHER |
|------------|-------|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | ANALYSIS NOT REQUIRED |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 3 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-01 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-JAN-19 |
|--------------------|-------------|

---

|                   |   |
|-------------------|---|
| Timepoint-minutes | 0 |
|-------------------|---|

---

|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

---

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:59**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

3

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:59**

**Generated On: 20 Jul 2016 11:47:42**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05112430000099 |
|----------------|----------------|

---

|         |     |
|---------|-----|
| Analyte | NIC |
|---------|-----|

---

|             |        |
|-------------|--------|
| Sample type | PLASMA |
|-------------|--------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |       |
|------------|-------|
| Lab Status | OTHER |
|------------|-------|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | ANALYSIS NOT REQUIRED |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 3 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-01 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-JAN-19 |
|--------------------|-------------|

---

|                   |   |
|-------------------|---|
| Timepoint-minutes | 0 |
|-------------------|---|

---

|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

---

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 3**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:46:59**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

3

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Date of Visit**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:01**

**Generated On: 20 Jul 2016 11:47:42**

---

Date of Visit

20 JAN 2014  
DD/MMM/YYYY

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Vital Signs**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:01**

**Generated On: 20 Jul 2016 11:47:42**

---

Were Vitals Signs assessed?

Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

Has the subject smoked within 15 minutes prior to  
assessment

No ☒

---

Time of assessment

09:50  
hour:min 24-hour clock

---

Pulse rate

85  
beats per minute

---

Respiratory rate

14  
breaths per minute

---

Blood Pressure (systolic)

102  
mmHg

---

Blood Pressure (diastolic)

62  
mmHg

---

Vital Signs Position of Subject

Supine ☒

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Socio-Economic Status**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:01**

**Generated On: 20 Jul 2016 11:47:42**

---

Was paper questionnaire used? Yes ☒

---

Reason not done \_\_\_\_\_

---

Date 20 JAN 2014  
DD/MMM/YYYY

---

Time 06:44  
hour:min 24-hour clock

---

Q1. What is the highest level of education you have completed? College Graduate ☒

---

Q2. What is your current occupational status? Other ☒

---

SPECIFY SMALL BUSINESS

---

Q3. How many people are currently living in your household, including yourself? 3

---

Q4. Of these people, how many are children? 0

---

Q5. Of these people, how many are adults? 3

---

Q6. Of the adults, how many bring income into the household? 3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Socio-Economic Status**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:01**

**Generated On: 20 Jul 2016 11:47:42**

---

Q7. Which of these categories best describes your total combined family income for the past 12 months? This should include income (before taxes) from all sources, wages, rent from properties, social security, disability and/or veteran's benefits, unemployment benefits, workman's compensation, help from relatives (including child payments and alimony), and so on.

\$30,000 through \$44,999 ☒

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Plasma Nicotine Sample**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:00**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 20 JAN 2014 |
|---------------------|-------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 20:36 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Plasma Cotinine Sample**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:00**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 20 JAN 2014 |
|---------------------|-------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 20:36 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: CoHb Blood Sample**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:00**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 20 JAN 2014 |
|---------------------|-------------|

---

|           |  |
|-----------|--|
| Timepoint | 20:00 - 21:30 <input checked="" type="radio"/> |
|-----------|--|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 20:36 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: CO Breath Test (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:01**

**Generated On: 20 Jul 2016 11:47:42**

---

|                     |       |
|---------------------|-------|
| Assessment not done | False |
|---------------------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                |   |
|----------------|---|
| Scheduled Time | Within 15 min prior to smoking <input checked="" type="radio"/> |
|----------------|---|

---

|   |       |
|---|-------|
| Actual Time of Assessment<br>hour:min 24-hour clock | 06:49 |
|---|-------|

---

|             |   |
|-------------|---|
| Result(ppm) | 1 |
|-------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: CO Breath Test (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:01**

**Generated On: 20 Jul 2016 11:47:42**

---

|                     |       |
|---------------------|-------|
| Assessment not done | False |
|---------------------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                |   |
|----------------|---|
| Scheduled Time | 12:00 - 13:30  |
|----------------|---|

---

|   |       |
|---|-------|
| Actual Time of Assessment<br>hour:min 24-hour clock | 12:11 |
|---|-------|

---

|             |   |
|-------------|---|
| Result(ppm) | 1 |
|-------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: CO Breath Test (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:01**

**Generated On: 20 Jul 2016 11:47:42**

---

|                     |       |
|---------------------|-------|
| Assessment not done | False |
|---------------------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                |  |
|----------------|--|
| Scheduled Time | 16:00 - 17:30 <input checked="" type="radio"/> |
|----------------|--|

---

|   |       |
|---|-------|
| Actual Time of Assessment<br>hour:min 24-hour clock | 16:51 |
|---|-------|

---

|             |   |
|-------------|---|
| Result(ppm) | 1 |
|-------------|---|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: CO Breath Test (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:01**

**Generated On: 20 Jul 2016 11:47:42**

---

|                     |       |
|---------------------|-------|
| Assessment not done | False |
|---------------------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                |   |
|----------------|---|
| Scheduled Time | 20:00 - 21:30  |
|----------------|---|

---

|   |       |
|---|-------|
| Actual Time of Assessment<br>hour:min 24-hour clock | 21:16 |
|---|-------|

---

|             |   |
|-------------|---|
| Result(ppm) | 1 |
|-------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: 24 hour urine collections**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:01**

**Generated On: 20 Jul 2016 11:47:42**

---

|            |                        |
|------------|------------------------|
| Start Time | 06:08                  |
|            | hour:min 24-hour clock |

---

|          |             |
|----------|-------------|
| End Date | 21 JAN 2014 |
|          | DD/MMM/YYYY |

---

|          |                        |
|----------|------------------------|
| End Time | 06:15                  |
|          | hour:min 24-hour clock |

---

|        |      |
|--------|------|
| Volume | 1504 |
|        | mL   |

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Sample Urine Collection**

**Generated On: 20 Jul 2016 11:47:42**

---

Were samples for 24h collected?

Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

How many primary tubes were collected?

10

---

How many back up tubes were collected?

12

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:02**

**Generated On: 20 Jul 2016 11:47:42**

---

|               |         |
|---------------|---------|
| Date of Birth | (b) (6) |
|---------------|---------|

---

|                                   |                            |
|-----------------------------------|----------------------------|
| Date of assessment<br>DD/MMM/YYYY | 2014 JAN 20<br>DD/MMM/YYYY |
|-----------------------------------|----------------------------|

---

|                    |                                 |
|--------------------|---------------------------------|
| Time of assessment | 06:24<br>hour:min 24-hour clock |
|--------------------|---------------------------------|

---

|                   |  |
|-------------------|--|
| Assessment Status | Completed <input checked="" type="radio"/> |
|-------------------|--|

---

Please indicate for each of the items below, how you have been feeling over the past 24 hours

---

|   |                            |
|---|----------------------------|
| How have you been feeling over the past 24 hours? | None <input type="radio"/> |
|---|----------------------------|

1. Angry, irritable, frustrated

---

|   |                            |
|---|----------------------------|
| How have you been feeling over the past 24 hours? | None <input type="radio"/> |
|---|----------------------------|

2. Anxious, nervous

---

|   |                            |
|---|----------------------------|
| How have you been feeling over the past 24 hours? | None <input type="radio"/> |
|---|----------------------------|

3. Depressed Mood, sad

---

|   |                            |
|---|----------------------------|
| How have you been feeling over the past 24 hours? | Mild <input type="radio"/> |
|---|----------------------------|

4. Desire or craving to smoke

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:02**

**Generated On: 20 Jul 2016 11:47:42**

---

How have you been feeling over the past 24 hours? None ☐

5. Difficulty concentrating

---

How have you been feeling over the past 24 hours? Moderate ☐

6. Increased appetite, hungry, weight gain

---

How have you been feeling over the past 24 hours? Slight ☐

7. Insomnia, sleep problems, awakening at night

---

How have you been feeling over the past 24 hours? Slight ☐

8. Restless

---

How have you been feeling over the past 24 hours? None ☐

9. Impatient

---

How have you been feeling over the past 24 hours? Slight ☐

10. Constipation

---

How have you been feeling over the past 24 hours? None ☐

11. Dizziness

---

How have you been feeling over the past 24 hours? None ☐

12. Coughing

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:02**

**Generated On: 20 Jul 2016 11:47:42**

---

How have you been feeling over the past 24 hours?

None ☐

13. Dreaming or nightmares

---

How have you been feeling over the past 24 hours?

None ☐

14. Nausea

---

How have you been feeling over the past 24 hours?

None ☐

15. Sore Throat

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Cough Assessment**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:02**

**Generated On: 20 Jul 2016 11:47:42**

---

|               |         |
|---------------|---------|
| Date of Birth | (b) (6) |
|---------------|---------|

---

---

|                                   |                            |
|-----------------------------------|----------------------------|
| Date of assessment<br>DD/MMM/YYYY | 2014 JAN 20<br>DD/MMM/YYYY |
|-----------------------------------|----------------------------|

---

---

|                    |                                 |
|--------------------|---------------------------------|
| Time of assessment | 06:23<br>hour:min 24-hour clock |
|--------------------|---------------------------------|

---

---

|                   |  |
|-------------------|--|
| Assessment Status | Completed <input checked="" type="radio"/> |
|-------------------|--|

---

---

|   |                                     |
|---|-------------------------------------|
| Have you experienced a regular need to cough e.g.<br>coughing several times in the last 24 hrs? | No <input checked="" type="radio"/> |
|---|-------------------------------------|

---

If YES, please answer the following questions:

---

---

|   |    |
|---|----|
| First Question: Cough Impact Scale<br>How much is your cough bothering you? | -9 |
|---|----|

---

---

|   |   |
|---|---|
| Second Question: Cough Intensity Scale:<br>How intense is your cough? | Not Applicable <input checked="" type="radio"/> |
|---|---|

---

---

|   |   |
|---|---|
| Third Question: Cough Frequency Scale:<br>How frequently do you normally have to cough each<br>day? | Not Applicable <input checked="" type="radio"/> |
|---|---|

---

---

|   |   |
|---|---|
| Fourth Question: Sputum Production<br>To what extent do you produce sputum when coughing? | Not Applicable <input checked="" type="radio"/> |
|---|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Lab\_BU\_COHB (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:04**

**Generated On: 20 Jul 2016 11:47:42**

|                               |                       |
|-------------------------------|-----------------------|
| Sample Barcode                | 05115150000103        |
| Analyte                       | CARBOXYHEMOGLOBIN     |
| Sample type                   | BLOOD                 |
| Result                        | .                     |
| Result Unit                   | %                     |
| Lab Status                    | OTHER                 |
| Sample comment                | ANALYSIS NOT REQUIRED |
| Detection method              | SPECTROPHOTOMETRIC    |
| Lower limit of quantification | 0.500                 |
| Planned time point (Hour)     | 20                    |
| Day of Visit                  | 4                     |
| Celerion Study Number         | AA99128-16            |
| Date of Collection            | 2014-JAN-20           |
| Timepoint-minutes             |                       |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Lab\_BU\_COHB (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:04**

**Generated On: 20 Jul 2016 11:47:42**

---

Start Day (24 hour urine only) \_\_\_\_\_

---

End Day (24 hour Urine Only) \_\_\_\_\_

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:02**

**Generated On: 20 Jul 2016 11:47:42**

|  |   |
|--|---|
| Date of Birth  | (b) (6)                                     |
| Date of assessment<br>DD/MMM/YYYY                        | 2014 JAN 20<br>DD/MMM/YYYY                  |
| Time of assessment                                       | 20:07<br>hour:min 24-hour clock             |
| Assessment Status  | Completed <input checked="" type="radio"/>  |
| 1. Was smoking satisfying?                               | Moderately <input checked="" type="radio"/> |
| 2. Did cigarettes taste good?                            | Moderately <input checked="" type="radio"/> |
| 3. Did you enjoy the sensation in your throat and chest? | Little <input checked="" type="radio"/>     |
| 4. Did smoking calm you down?                            | Moderately <input checked="" type="radio"/> |
| 5. Did smoking make you feel more awake?                 | Moderately <input checked="" type="radio"/> |
| 6. Did smoking make you feel less irritable?             | Little <input checked="" type="radio"/>     |
| 7. Did smoking help you concentrate?                     | Not at all <input checked="" type="radio"/> |
| 8. Did smoking reduce your hunger for food?              | Little <input checked="" type="radio"/>     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:02**

**Generated On: 20 Jul 2016 11:47:42**

---

9. Did smoking make you dizzy? Very little ☐

---

10. Did smoking make you nauseous? Not at all ☐

---

11. Did smoking immediately relieve your craving for a cigarette? Moderately ☐

---

12. Did you enjoy smoking? Moderately ☐

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Human Smoking Topography Questionnaire**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:01**

**Generated On: 20 Jul 2016 11:47:42**

---

|      |  |
|------|--|
| Type | HUMAN SMOKING<br>TOPOGRAPHY<br>QUESTIONNAIRE |
|------|--|

---

---

|                               |                           |
|-------------------------------|---------------------------|
| Was paper questionnaire used? | Yes <input type="radio"/> |
|-------------------------------|---------------------------|

---

---

|                 |  |
|-----------------|--|
| Reason not done |  |
|-----------------|--|

---

---

|                    |                            |
|--------------------|----------------------------|
| Date of assessment | 20 JAN 2014<br>DD/MMM/YYYY |
|--------------------|----------------------------|

---

---

|                    |                                 |
|--------------------|---------------------------------|
| Time of assessment | 20:12<br>hour:min 24-hour clock |
|--------------------|---------------------------------|

---

---

How do you agree with the following sentences/affirmations :

---

---

|  |   |
|--|---|
| 1. The smoking of the conventional cigarettes/products is different with the device. | Strongly disagree <input type="radio"/> |
|--|---|

---

---

|   |   |
|---|---|
| If you agree or strongly agree, please describe : | DOES NOT EFFECT THE<br>SMOKING ASPECT HOWEVER,<br>DEVICE TO HEAVY ON STICK<br>CONSTANT BREAKING OF<br>CIGARETTE |
|---|---|

---

---

|   |                                      |
|---|--------------------------------------|
| 2. You enjoy smoking with the device as much as without it. | Strongly agree <input type="radio"/> |
|---|--------------------------------------|

---

---

|   |  |
|---|--|
| If you disagree or strongly disagree, please describe : |  |
|---|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Human Smoking Topography Questionnaire**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:01**

**Generated On: 20 Jul 2016 11:47:42**

---

3. The taste of the conventional cigarettes/products is  
different with the device.

Strongly disagree ☒

---

If you agree or strongly agree, please describe :

TASTE IS THE SAME BETTER  
PULL OF MENTHOL FROM  
STICK

---

4. The device is easy to use.

Strongly agree ☒

---

If you disagree or strongly disagree, please describe : \_\_\_\_\_

---

5. Your smoking is disturbed by the device.

Strongly agree ☒

---

If you agree or strongly agree, please describe : \_\_\_\_\_

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Questionnaire on smoking urges (QSU)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:01**

**Generated On: 20 Jul 2016 11:47:42**

---

|      |     |
|------|-----|
| Type | QSU |
|------|-----|

---

|               |         |
|---------------|---------|
| Date of Birth | (b) (6) |
|---------------|---------|

---

|                    |             |
|--------------------|-------------|
| Date of assessment | 2014 JAN 20 |
|--------------------|-------------|

DD/MMM/YYYY

---

|                    |       |
|--------------------|-------|
| Time of assessment | 20:05 |
|--------------------|-------|

hour:min 24-hour clock

---

|                   |  |
|-------------------|--|
| Assessment Status | Completed <input checked="" type="radio"/> |
|-------------------|--|

---

|  |  |
|--|--|
| 1. I have a desire for a cigarette right now | Do not agree or disagree <input type="radio"/> |
|--|--|

---

|   |  |
|---|--|
| 2. Nothing would be better than smoking a cigarette right now | Do not agree or disagree <input type="radio"/> |
|---|--|

---

|   |  |
|---|--|
| 3. If it were possible I would probably smoke now | Agree <input checked="" type="radio"/> |
|---|--|

---

|   |                                |
|---|--------------------------------|
| 4. I could control things better right now if I could smoke | Disagree <input type="radio"/> |
|---|--------------------------------|

---

|  |  |
|--|--|
| 5. All I want right now is a cigarette | Do not agree or disagree <input type="radio"/> |
|--|--|

---

|                                   |                                      |
|-----------------------------------|--------------------------------------|
| 6. I have an urge for a cigarette | Somewhat agree <input type="radio"/> |
|-----------------------------------|--------------------------------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Questionnaire on smoking urges (QSU)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:01**

**Generated On: 20 Jul 2016 11:47:42**

---

7. A cigarette would taste good now Somewhat agree ☐

---

8. I would do almost anything for a cigarette now Somewhat disagree ☐

---

9. Smoking would make me less depressed Strongly disagree ☐

---

10. I am going to smoke as soon as possible Somewhat agree ☐

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (CEMA, HPMa, HBMA)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:04**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:04**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112450000095        |
| Analyte                   | HPMA                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 4                     |
| Celerion Study Number     | AA99128-03            |
| Date of Collection        | 2014-JAN-20           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 4                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:04**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

5

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:04**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112450000095        |
| Analyte                   | CEMA                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 4                     |
| Celerion Study Number     | AA99128-03            |
| Date of Collection        | 2014-JAN-20           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 4                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:04**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

---

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (CEMA, HPMa, HBMA) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:04**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112450000095        |
| Analyte                   | HBMA                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 4                     |
| Celerion Study Number     | AA99128-03            |
| Date of Collection        | 2014-JAN-20           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 4                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:04**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

5

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (NNN, NNAL)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:02**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (NNN, NNAL) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:02**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112460000095        |
| Analyte                   | NNAL                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | PG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 4                     |
| Celerion Study Number     | AA99128-04            |
| Date of Collection        | 2014-JAN-20           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 4                     |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (NNN, NNAL) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:02**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

5

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (NNN, NNAL) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:02**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112460000095        |
| Analyte                   | NNN                   |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | PG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 4                     |
| Celerion Study Number     | AA99128-04            |
| Date of Collection        | 2014-JAN-20           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 4                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (NNN, NNAL) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:02**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

5

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (HEMA)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:03**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (HEMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:03**

**Generated On: 20 Jul 2016 11:47:42**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05112470000095 |
|----------------|----------------|

---

|         |      |
|---------|------|
| Analyte | HEMA |
|---------|------|

---

|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |       |
|------------|-------|
| Lab Status | OTHER |
|------------|-------|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | ANALYSIS NOT REQUIRED |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 4 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-05 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-JAN-20 |
|--------------------|-------------|

---

|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

---

|                 |   |
|-----------------|---|
| Urine Start Day | 4 |
|-----------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (HEMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:03**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

5

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:05**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:05**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112480000062        |
| Analyte                   | COT                   |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 4                     |
| Celerion Study Number     | AA99128-06            |
| Date of Collection        | 2014-JAN-22           |
| Timepoint-minutes         |                       |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:05**

**Generated On: 20 Jul 2016 11:47:42**

---

|                 |   |
|-----------------|---|
| Urine Start Day | 4 |
|-----------------|---|

---

|               |   |
|---------------|---|
| Urine End Day | 5 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:05**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112480000062        |
| Analyte                   | COT-GLUC              |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 4                     |
| Celerion Study Number     | AA99128-06            |
| Date of Collection        | 2014-JAN-22           |
| Timepoint-minutes         |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:05**

**Generated On: 20 Jul 2016 11:47:42**

---

|                 |   |
|-----------------|---|
| Urine Start Day | 4 |
|-----------------|---|

---

|               |   |
|---------------|---|
| Urine End Day | 5 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:05**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112480000062        |
| Analyte                   | NIC                   |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 4                     |
| Celerion Study Number     | AA99128-06            |
| Date of Collection        | 2014-JAN-22           |
| Timepoint-minutes         |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:05**

**Generated On: 20 Jul 2016 11:47:42**

---

|                 |   |
|-----------------|---|
| Urine Start Day | 4 |
|-----------------|---|

---

|               |   |
|---------------|---|
| Urine End Day | 5 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:05**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112480000062        |
| Analyte                   | NIC-GLUC              |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 4                     |
| Celerion Study Number     | AA99128-06            |
| Date of Collection        | 2014-JAN-22           |
| Timepoint-minutes         |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:05**

**Generated On: 20 Jul 2016 11:47:42**

---

|                 |   |
|-----------------|---|
| Urine Start Day | 4 |
|-----------------|---|

---

|               |   |
|---------------|---|
| Urine End Day | 5 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:05**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112480000062        |
| Analyte                   | THCOT                 |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 4                     |
| Celerion Study Number     | AA99128-06            |
| Date of Collection        | 2014-JAN-22           |
| Timepoint-minutes         |                       |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:05**

**Generated On: 20 Jul 2016 11:47:42**

---

|                 |   |
|-----------------|---|
| Urine Start Day | 4 |
|-----------------|---|

---

|               |   |
|---------------|---|
| Urine End Day | 5 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:05**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112480000062        |
| Analyte                   | THCOT-GLUC            |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 4                     |
| Celerion Study Number     | AA99128-06            |
| Date of Collection        | 2014-JAN-22           |
| Timepoint-minutes         |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:05**

**Generated On: 20 Jul 2016 11:47:42**

---

|                 |   |
|-----------------|---|
| Urine Start Day | 4 |
|-----------------|---|

---

|               |   |
|---------------|---|
| Urine End Day | 5 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (3-OH BaP)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:05**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (3-OH BaP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:05**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112490000095        |
| Analyte                   | 3-OH BAP              |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | FG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 4                     |
| Celerion Study Number     | AA99128-07            |
| Date of Collection        | 2014-JAN-20           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 4                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (3-OH BaP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:05**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

5

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:05**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:05**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112510000095        |
| Analyte                   | 1-NA                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | PG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 4                     |
| Celerion Study Number     | AA99128-09            |
| Date of Collection        | 2014-JAN-20           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 4                     |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:05**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

---

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:05**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112510000095        |
| Analyte                   | 2-NA                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | PG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 4                     |
| Celerion Study Number     | AA99128-09            |
| Date of Collection        | 2014-JAN-20           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 4                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:05**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

---

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:05**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112510000095        |
| Analyte                   | 4-ABP                 |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | PG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 4                     |
| Celerion Study Number     | AA99128-09            |
| Date of Collection        | 2014-JAN-20           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 4                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:05**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

---

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:05**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112510000095        |
| Analyte                   | O-TOL                 |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | PG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 4                     |
| Celerion Study Number     | AA99128-09            |
| Date of Collection        | 2014-JAN-20           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 4                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:05**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

---

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (1-OHP)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:05**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (1-OHP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:05**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05115190001184        |
| Analyte                   | 1-OHP                 |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | PG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 4                     |
| Celerion Study Number     | AA99598-03            |
| Date of Collection        | 2014-JAN-20           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 4                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (1-OHP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:05**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

5

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (SPMA, SBMA)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:03**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (SPMA, SBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:03**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05115170000095        |
| Analyte                   | SBMA                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 4                     |
| Celerion Study Number     | AA99598-01            |
| Date of Collection        | 2014-JAN-20           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 4                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (SPMA, SBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:03**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

5

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (SPMA, SBMA) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:03**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05115170000095        |
| Analyte                   | SPMA                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 4                     |
| Celerion Study Number     | AA99598-01            |
| Date of Collection        | 2014-JAN-20           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 4                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (SPMA, SBMA) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:03**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

5

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (MHBMA)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:03**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (MHBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:03**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05115180000095        |
| Analyte                   | MHBMA                 |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 4                     |
| Celerion Study Number     | AA99598-02            |
| Date of Collection        | 2014-JAN-20           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 4                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (MHBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:03**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

---

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (Creatinine)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:05**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (Creatinine) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:05**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05115160000095        |
| Analyte                   | CREATININE            |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | MG/DL                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | SPECTROPHOTOMETRIC    |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 4                     |
| Celerion Study Number     | AA99128-14            |
| Date of Collection        | 2014-JAN-20           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 4                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Urine (Creatinine) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:05**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

5

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Plasma (Nic, Cot, tHCot)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:03**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

PLASMA

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:03**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112430000100        |
| Analyte                   | COT                   |
| Sample type               | PLASMA                |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 4                     |
| Celerion Study Number     | AA99128-01            |
| Date of Collection        | 2014-JAN-20           |
| Timepoint-minutes         | 0                     |
| Urine Start Day           |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:03**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

4

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:03**

**Generated On: 20 Jul 2016 11:47:42**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05112430000100 |
|----------------|----------------|

---

|         |     |
|---------|-----|
| Analyte | NIC |
|---------|-----|

---

|             |        |
|-------------|--------|
| Sample type | PLASMA |
|-------------|--------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |       |
|------------|-------|
| Lab Status | OTHER |
|------------|-------|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | ANALYSIS NOT REQUIRED |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 4 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-01 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-JAN-20 |
|--------------------|-------------|

---

|                   |   |
|-------------------|---|
| Timepoint-minutes | 0 |
|-------------------|---|

---

|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 4**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:03**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

4

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Date of Visit**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:12**

**Generated On: 20 Jul 2016 11:47:42**

---

Date of Visit

21 JAN 2014  
DD/MMM/YYYY

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Vital Signs**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:12**

**Generated On: 20 Jul 2016 11:47:42**

---

Were Vitals Signs assessed? Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

Has the subject smoked within 15 minutes prior to assessment No ☒

---

Time of assessment 10:26  
hour:min 24-hour clock

---

Pulse rate 80  
beats per minute

---

Respiratory rate 16  
breaths per minute

---

Blood Pressure (systolic) 110  
mmHg

---

Blood Pressure (diastolic) 70  
mmHg

---

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Plasma Nicotine Samples <Day 5> (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:13**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 21 JAN 2014 |
|---------------------|-------------|

---

|                |   |
|----------------|---|
| Scheduled Time | T0 -15 min <input checked="" type="radio"/> |
|----------------|---|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 06:48 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Plasma Nicotine Samples <Day 5> (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:13**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 21 JAN 2014 |
|---------------------|-------------|

---

|                |                                     |
|----------------|-------------------------------------|
| Scheduled Time | T1 <input checked="" type="radio"/> |
|----------------|-------------------------------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 08:46 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Plasma Nicotine Samples <Day 5> (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:13**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 21 JAN 2014 |
|---------------------|-------------|

---

|                |                                     |
|----------------|-------------------------------------|
| Scheduled Time | T2 <input checked="" type="radio"/> |
|----------------|-------------------------------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 10:46 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Plasma Nicotine Samples <Day 5> (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:13**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 21 JAN 2014 |
|---------------------|-------------|

---

|                |                                     |
|----------------|-------------------------------------|
| Scheduled Time | T3 <input checked="" type="radio"/> |
|----------------|-------------------------------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 12:46 |
|--------------------------------|-------|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Plasma Nicotine Samples <Day 5> (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:13**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 21 JAN 2014 |
|---------------------|-------------|

---

|                |                                     |
|----------------|-------------------------------------|
| Scheduled Time | T4 <input checked="" type="radio"/> |
|----------------|-------------------------------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 14:46 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Plasma Nicotine Samples <Day 5> (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:13**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 21 JAN 2014 |
|---------------------|-------------|

---

|                |                                     |
|----------------|-------------------------------------|
| Scheduled Time | T5 <input checked="" type="radio"/> |
|----------------|-------------------------------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 16:46 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Plasma Nicotine Samples <Day 5> (7)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:13**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 21 JAN 2014 |
|---------------------|-------------|

---

|                |                                     |
|----------------|-------------------------------------|
| Scheduled Time | T6 <input checked="" type="radio"/> |
|----------------|-------------------------------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 18:46 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Plasma Nicotine Samples <Day 5> (8)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:13**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 21 JAN 2014 |
|---------------------|-------------|

---

|                |                                     |
|----------------|-------------------------------------|
| Scheduled Time | T7 <input checked="" type="radio"/> |
|----------------|-------------------------------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 20:46 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Plasma Nicotine Samples <Day 5> (9)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:13**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 21 JAN 2014 |
|---------------------|-------------|

---

|                |                                     |
|----------------|-------------------------------------|
| Scheduled Time | T8 <input checked="" type="radio"/> |
|----------------|-------------------------------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 22:46 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Plasma Cotinine Samples <Day 5> (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:13**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 21 JAN 2014 |
|---------------------|-------------|

---

|                |   |
|----------------|---|
| Scheduled Time | T0 -15 min <input checked="" type="radio"/> |
|----------------|---|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 06:48 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Plasma Cotinine Samples <Day 5> (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:13**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 21 JAN 2014 |
|---------------------|-------------|

---

|                |                                     |
|----------------|-------------------------------------|
| Scheduled Time | T1 <input checked="" type="radio"/> |
|----------------|-------------------------------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 08:46 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Plasma Cotinine Samples <Day 5> (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:13**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 21 JAN 2014 |
|---------------------|-------------|

---

|                |                                     |
|----------------|-------------------------------------|
| Scheduled Time | T2 <input checked="" type="radio"/> |
|----------------|-------------------------------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 10:46 |
|--------------------------------|-------|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Plasma Cotinine Samples <Day 5> (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:13**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 21 JAN 2014 |
|---------------------|-------------|

---

|                |                                     |
|----------------|-------------------------------------|
| Scheduled Time | T3 <input checked="" type="radio"/> |
|----------------|-------------------------------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 12:46 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Plasma Cotinine Samples <Day 5> (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:13**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 21 JAN 2014 |
|---------------------|-------------|

---

|                |                                     |
|----------------|-------------------------------------|
| Scheduled Time | T4 <input checked="" type="radio"/> |
|----------------|-------------------------------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 14:46 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Plasma Cotinine Samples <Day 5> (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:13**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 21 JAN 2014 |
|---------------------|-------------|

---

|                |                                     |
|----------------|-------------------------------------|
| Scheduled Time | T5 <input checked="" type="radio"/> |
|----------------|-------------------------------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 16:46 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Plasma Cotinine Samples <Day 5> (7)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:13**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 21 JAN 2014 |
|---------------------|-------------|

---

|                |                                     |
|----------------|-------------------------------------|
| Scheduled Time | T6 <input checked="" type="radio"/> |
|----------------|-------------------------------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 18:46 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Plasma Cotinine Samples <Day 5> (8)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:13**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 21 JAN 2014 |
|---------------------|-------------|

---

|                |                                     |
|----------------|-------------------------------------|
| Scheduled Time | T7 <input checked="" type="radio"/> |
|----------------|-------------------------------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 20:46 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Plasma Cotinine Samples <Day 5> (9)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:13**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 21 JAN 2014 |
|---------------------|-------------|

---

|                |                                     |
|----------------|-------------------------------------|
| Scheduled Time | T8 <input checked="" type="radio"/> |
|----------------|-------------------------------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 22:46 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: CoHb Blood Sample(CC/THS) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:13**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 21 JAN 2014 |
|---------------------|-------------|

---

|                |   |
|----------------|---|
| Scheduled Time | Within 15 min prior to smoking <input checked="" type="radio"/> |
|----------------|---|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 06:48 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: CoHb Blood Sample(CC/THS) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:13**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 21 JAN 2014 |
|---------------------|-------------|

---

|                |  |
|----------------|--|
| Scheduled Time | 12:00 - 13:30 <input checked="" type="radio"/> |
|----------------|--|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 12:46 |
|--------------------------------|-------|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: CoHb Blood Sample(CC/THS) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:13**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 21 JAN 2014 |
|---------------------|-------------|

---

|                |  |
|----------------|--|
| Scheduled Time | 16:00 - 17:30 <input checked="" type="radio"/> |
|----------------|--|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 16:16 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: CoHb Blood Sample(CC/THS) (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:13**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 21 JAN 2014 |
|---------------------|-------------|

---

|                |  |
|----------------|--|
| Scheduled Time | 20:00 - 21:30 <input checked="" type="radio"/> |
|----------------|--|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 20:46 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: CO Breath Test (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:12**

**Generated On: 20 Jul 2016 11:47:42**

---

|                     |       |
|---------------------|-------|
| Assessment not done | False |
|---------------------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                |   |
|----------------|---|
| Scheduled Time | Within 15 min prior to smoking <input checked="" type="radio"/> |
|----------------|---|

---

|   |       |
|---|-------|
| Actual Time of Assessment<br>hour:min 24-hour clock | 06:44 |
|---|-------|

---

|             |   |
|-------------|---|
| Result(ppm) | 1 |
|-------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: CO Breath Test (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:12**

**Generated On: 20 Jul 2016 11:47:42**

---

|                     |       |
|---------------------|-------|
| Assessment not done | False |
|---------------------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                |   |
|----------------|---|
| Scheduled Time | 12:00 - 13:30  |
|----------------|---|

---

|   |       |
|---|-------|
| Actual Time of Assessment<br>hour:min 24-hour clock | 12:07 |
|---|-------|

---

|             |   |
|-------------|---|
| Result(ppm) | 1 |
|-------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: CO Breath Test (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:12**

**Generated On: 20 Jul 2016 11:47:42**

---

|                     |       |
|---------------------|-------|
| Assessment not done | False |
|---------------------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                |  |
|----------------|--|
| Scheduled Time | 16:00 - 17:30 <input checked="" type="radio"/> |
|----------------|--|

---

|   |       |
|---|-------|
| Actual Time of Assessment<br>hour:min 24-hour clock | 16:48 |
|---|-------|

---

|             |   |
|-------------|---|
| Result(ppm) | 2 |
|-------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: CO Breath Test (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:12**

**Generated On: 20 Jul 2016 11:47:42**

---

|                     |       |
|---------------------|-------|
| Assessment not done | False |
|---------------------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                |  |
|----------------|--|
| Scheduled Time | 20:00 - 21:30 <input checked="" type="radio"/> |
|----------------|--|

---

|   |       |
|---|-------|
| Actual Time of Assessment<br>hour:min 24-hour clock | 20:35 |
|---|-------|

---

|             |   |
|-------------|---|
| Result(ppm) | 3 |
|-------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Day 5**

**Form: CYP1A2 activity Sample**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:06**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                |                        |
|--------------------------------|------------------------|
| Time of caffeine tablet intake | 10:16                  |
|                                | hour:min 24-hour clock |

---

|                            |       |
|----------------------------|-------|
| Sample collection Not Done | False |
|----------------------------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

| Date of sample collection<br>DD/MMM/YYYY | Time of sample collection<br>hour:min 24-hour clock | Parameter    |
|--|---|--------------|
| 21 JAN 2014                              | 16:16   | Caffeine     |
| 21 JAN 2014                              | 16:16   | Paraxanthine |

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: 24 hour urine collections**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:12**

**Generated On: 20 Jul 2016 11:47:42**

---

|            |                        |
|------------|------------------------|
| Start Time | 06:15                  |
|            | hour:min 24-hour clock |

---

|          |             |
|----------|-------------|
| End Date | 22 JAN 2014 |
|          | DD/MMM/YYYY |

---

|          |                        |
|----------|------------------------|
| End Time | 06:05                  |
|          | hour:min 24-hour clock |

---

|        |      |
|--------|------|
| Volume | 1166 |
|        | mL   |

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Sample Urine Collection**

**Generated On: 20 Jul 2016 11:47:42**

---

Were samples for 24h collected?

Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

How many primary tubes were collected?

11

---

How many back up tubes were collected?

15

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:14**

**Generated On: 20 Jul 2016 11:47:42**

---

Date of Birth

(b) (6)

---

Date of assessment  
DD/MMM/YYYY

2014 JAN 21  
DD/MMM/YYYY

---

Time of assessment

06:03  
hour:min 24-hour clock

---

Assessment Status

Completed ☒

---

Please indicate for each of the items below, how you have been feeling over the past 24 hours

---

How have you been feeling over the past 24 hours?

None ☐

1. Angry, irritable, frustrated

---

How have you been feeling over the past 24 hours?

None ☐

2. Anxious, nervous

---

How have you been feeling over the past 24 hours?

None ☐

3. Depressed Mood, sad

---

How have you been feeling over the past 24 hours?

Moderate ☐

4. Desire or craving to smoke

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:14**

**Generated On: 20 Jul 2016 11:47:42**

---

How have you been feeling over the past 24 hours? None ☐

5. Difficulty concentrating

---

How have you been feeling over the past 24 hours? Mild ☐

6. Increased appetite, hungry, weight gain

---

How have you been feeling over the past 24 hours? None ☐

7. Insomnia, sleep problems, awakening at night

---

How have you been feeling over the past 24 hours? None ☐

8. Restless

---

How have you been feeling over the past 24 hours? None ☐

9. Impatient

---

How have you been feeling over the past 24 hours? Mild ☐

10. Constipation

---

How have you been feeling over the past 24 hours? None ☐

11. Dizziness

---

How have you been feeling over the past 24 hours? None ☐

12. Coughing

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:14**

**Generated On: 20 Jul 2016 11:47:42**

---

How have you been feeling over the past 24 hours?

None ☐

13. Dreaming or nightmares

---

How have you been feeling over the past 24 hours?

None ☐

14. Nausea

---

How have you been feeling over the past 24 hours?

None ☐

15. Sore Throat

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Day 5**

**Form: Cough Assessment**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:15**

**Generated On: 20 Jul 2016 11:47:42**

---

Date of Birth

(b) (6)

---

Date of assessment  
DD/MMM/YYYY

2014 JAN 21  
DD/MMM/YYYY

---

Time of assessment

06:02  
hour:min 24-hour clock

---

Assessment Status

Completed ☒

---

Have you experienced a regular need to cough e.g.  
coughing several times in the last 24 hrs?

No ☒

---

If YES, please answer the following questions:

---

First Question: Cough Impact Scale  
How much is your cough bothering you?

-9

---

Second Question: Cough Intensity Scale:  
How intense is your cough?

Not Applicable ☒

---

Third Question: Cough Frequency Scale:  
How frequently do you normally have to cough each  
day?

Not Applicable ☒

---

Fourth Question: Sputum Production  
To what extent do you produce sputum when coughing?

Not Applicable ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Lab\_BU\_COHB (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:17**

**Generated On: 20 Jul 2016 11:47:42**

|                               |                       |
|-------------------------------|-----------------------|
| Sample Barcode                | 05115150000104        |
| Analyte                       | CARBOXYHEMOGLOBIN     |
| Sample type                   | BLOOD                 |
| Result                        | .                     |
| Result Unit                   | %                     |
| Lab Status                    | OTHER                 |
| Sample comment                | ANALYSIS NOT REQUIRED |
| Detection method              | SPECTROPHOTOMETRIC    |
| Lower limit of quantification | 0.500                 |
| Planned time point (Hour)     | 6                     |
| Day of Visit                  | 5                     |
| Celerion Study Number         | AA99128-16            |
| Date of Collection            | 2014-JAN-21           |
| Timepoint-minutes             |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Lab\_BU\_COHB (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:17**

**Generated On: 20 Jul 2016 11:47:42**

---

Start Day (24 hour urine only)

---

End Day (24 hour Urine Only)

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Lab\_BU\_COHB (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:17**

**Generated On: 20 Jul 2016 11:47:42**

|                               |                       |
|-------------------------------|-----------------------|
| Sample Barcode                | 05115150000105        |
| Analyte                       | CARBOXYHEMOGLOBIN     |
| Sample type                   | BLOOD                 |
| Result                        | .                     |
| Result Unit                   | %                     |
| Lab Status                    | OTHER                 |
| Sample comment                | ANALYSIS NOT REQUIRED |
| Detection method              | SPECTROPHOTOMETRIC    |
| Lower limit of quantification | 0.500                 |
| Planned time point (Hour)     | 12                    |
| Day of Visit                  | 5                     |
| Celerion Study Number         | AA99128-16            |
| Date of Collection            | 2014-JAN-21           |
| Timepoint-minutes             |                       |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Lab\_BU\_COHB (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:17**

**Generated On: 20 Jul 2016 11:47:42**

---

Start Day (24 hour urine only) \_\_\_\_\_

---

End Day (24 hour Urine Only) \_\_\_\_\_

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Lab\_BU\_COHB (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:17**

**Generated On: 20 Jul 2016 11:47:42**

|                               |                       |
|-------------------------------|-----------------------|
| Sample Barcode                | 05115150000106        |
| Analyte                       | CARBOXYHEMOGLOBIN     |
| Sample type                   | BLOOD                 |
| Result                        | .                     |
| Result Unit                   | %                     |
| Lab Status                    | OTHER                 |
| Sample comment                | ANALYSIS NOT REQUIRED |
| Detection method              | SPECTROPHOTOMETRIC    |
| Lower limit of quantification | 0.500                 |
| Planned time point (Hour)     | 16                    |
| Day of Visit                  | 5                     |
| Celerion Study Number         | AA99128-16            |
| Date of Collection            | 2014-JAN-21           |
| Timepoint-minutes             |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Lab\_BU\_COHB (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:17**

**Generated On: 20 Jul 2016 11:47:42**

---

Start Day (24 hour urine only)

---

End Day (24 hour Urine Only)

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Lab\_BU\_COHB (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:17**

**Generated On: 20 Jul 2016 11:47:42**

|                               |                       |
|-------------------------------|-----------------------|
| Sample Barcode                | 05115150000107        |
| Analyte                       | CARBOXYHEMOGLOBIN     |
| Sample type                   | BLOOD                 |
| Result                        | .                     |
| Result Unit                   | %                     |
| Lab Status                    | OTHER                 |
| Sample comment                | ANALYSIS NOT REQUIRED |
| Detection method              | SPECTROPHOTOMETRIC    |
| Lower limit of quantification | 0.500                 |
| Planned time point (Hour)     | 20                    |
| Day of Visit                  | 5                     |
| Celerion Study Number         | AA99128-16            |
| Date of Collection            | 2014-JAN-21           |
| Timepoint-minutes             |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Lab\_BU\_COHB (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:17**

**Generated On: 20 Jul 2016 11:47:42**

---

Start Day (24 hour urine only) \_\_\_\_\_

---

End Day (24 hour Urine Only) \_\_\_\_\_

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:14**

**Generated On: 20 Jul 2016 11:47:42**

---

Date of Birth

(b) (6)

---

Date of assessment

2014 JAN 21  
DD/MMM/YYYY

DD/MMM/YYYY

---

Time of assessment

20:11  
hour:min 24-hour clock

---

Assessment Status

Completed ☒

---

1. Was smoking satisfying?

Moderately ☒

---

2. Did cigarettes taste good?

Moderately ☒

---

3. Did you enjoy the sensation in your throat and chest?

Little ☒

---

4. Did smoking calm you down?

Moderately ☒

---

5. Did smoking make you feel more awake?

Moderately ☒

---

6. Did smoking make you feel less irritable?

Very little ☒

---

7. Did smoking help you concentrate?

Not at all ☒

---

8. Did smoking reduce your hunger for food?

Moderately ☒

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:14**

**Generated On: 20 Jul 2016 11:47:42**

---

9. Did smoking make you dizzy? Not at all ☐

---

10. Did smoking make you nauseous? Not at all ☐

---

11. Did smoking immediately relieve your craving for a cigarette? Moderately ☐

---

12. Did you enjoy smoking? A lot ☐

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Behavioral Risk Factor Surveillance System Questionnaire**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:06**

**Generated On: 20 Jul 2016 11:47:42**

---

|      |  |
|------|--|
| Type | BEHAVIORAL RISK FACTOR<br>SURVEILLANCE SYSTEM<br>QUESTIONNAIRE |
|------|--|

---

|                               |                           |
|-------------------------------|---------------------------|
| Was paper questionnaire used? | Yes <input type="radio"/> |
|-------------------------------|---------------------------|

---

|                 |       |
|-----------------|-------|
| Reason not done | <hr/> |
|-----------------|-------|

---

|                    |                            |
|--------------------|----------------------------|
| Date of assessment | 21 JAN 2014<br>DD/MMM/YYYY |
|--------------------|----------------------------|

---

|                    |                                 |
|--------------------|---------------------------------|
| Time of assessment | 21:00<br>hour:min 24-hour clock |
|--------------------|---------------------------------|

---

|   |                           |
|---|---------------------------|
| Have you ever smoked 100 cigarettes or more in your life? | Yes <input type="radio"/> |
|---|---------------------------|

---

|  |                                 |
|--|---------------------------------|
| Do you now smoke cigarettes every day, some days, or not at all? | Every day <input type="radio"/> |
|--|---------------------------------|

---

|  |                          |
|--|--------------------------|
| During the past 12 months, have you stopped smoking for one day or longer because you were trying to quit smoking? | No <input type="radio"/> |
|--|--------------------------|

---

|  |       |
|--|-------|
| How long has it been since you last smoked a cigarette, even one or two puffs? | <hr/> |
|--|-------|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Behavioral Risk Factor Surveillance System Questionnaire**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:06**

**Generated On: 20 Jul 2016 11:47:42**

---

Do you currently use chewing tobacco, snuff, or snus  
every day, some days, or not at all?

Not at all ☐

NOTE: Snus (Swedish for snuff) is a moist smokeless  
tobacco, usually sold in small pouches that are placed  
under the lip against the gum.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Day 5**

**Form: Smoking Questionnaire (SQ)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:06**

**Generated On: 20 Jul 2016 11:47:42**

---

|      |                       |
|------|-----------------------|
| Type | SMOKING QUESTIONNAIRE |
|------|-----------------------|

---

|                               |                           |
|-------------------------------|---------------------------|
| Was paper questionnaire used? | Yes <input type="radio"/> |
|-------------------------------|---------------------------|

---

|                 |       |
|-----------------|-------|
| Reason not done | <hr/> |
|-----------------|-------|

---

|                    |                            |
|--------------------|----------------------------|
| Date of assessment | 21 JAN 2014<br>DD/MMM/YYYY |
|--------------------|----------------------------|

---

|                    |                                 |
|--------------------|---------------------------------|
| Time of assessment | 21:00<br>hour:min 24-hour clock |
|--------------------|---------------------------------|

---

|  |   |
|--|---|
| 1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)? | Daily smoker (at least one cigarette per day, disregarding religious fasting) <input type="radio"/> |
|--|---|

---

|  |                           |
|--|---------------------------|
| 2. Have you ever smoked 100 cigarettes or more in your life? | Yes <input type="radio"/> |
|--|---------------------------|

---

|  |                           |
|--|---------------------------|
| 3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day? | Yes <input type="radio"/> |
|--|---------------------------|

---

|   |          |
|---|----------|
| 4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly? | 25 Years |
|---|----------|

---

|   |  |
|---|--|
| 5. If you are an ex-smoker of cigarettes: For how long have you quit now? |  |
|---|--|

---

|       |       |
|-------|-------|
| Years | <hr/> |
|-------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Smoking Questionnaire (SQ)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:06**

**Generated On: 20 Jul 2016 11:47:42**

---

Months \_\_\_\_\_

---

Days \_\_\_\_\_

---

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?  
(Please add together any separate periods of quitting)

---

Years \_\_\_\_\_

---

Months \_\_\_\_\_

---

Days \_\_\_\_\_

---

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking? 305 MENTHOL 100'S

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Day 5**

**Form: Smoking Questionnaire (SQ) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:06**

**Generated On: 20 Jul 2016 11:47:42**

---

|      |                       |
|------|-----------------------|
| Type | SMOKING QUESTIONNAIRE |
|------|-----------------------|

---

|                               |                           |
|-------------------------------|---------------------------|
| Was paper questionnaire used? | Yes <input type="radio"/> |
|-------------------------------|---------------------------|

---

|                 |       |
|-----------------|-------|
| Reason not done | <hr/> |
|-----------------|-------|

---

|                    |                            |
|--------------------|----------------------------|
| Date of assessment | 21 JAN 2014<br>DD/MMM/YYYY |
|--------------------|----------------------------|

---

|                    |                                 |
|--------------------|---------------------------------|
| Time of assessment | 21:00<br>hour:min 24-hour clock |
|--------------------|---------------------------------|

---

|  |   |
|--|---|
| 1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)? | Daily smoker (at least one cigarette per day, disregarding religious fasting) <input type="radio"/> |
|--|---|

---

|  |                           |
|--|---------------------------|
| 2. Have you ever smoked 100 cigarettes or more in your life? | Yes <input type="radio"/> |
|--|---------------------------|

---

|  |                           |
|--|---------------------------|
| 3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day? | Yes <input type="radio"/> |
|--|---------------------------|

---

|   |          |
|---|----------|
| 4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly? | 25 Years |
|---|----------|

---

|   |  |
|---|--|
| 5. If you are an ex-smoker of cigarettes: For how long have you quit now? |  |
|---|--|

---

|       |       |
|-------|-------|
| Years | <hr/> |
|-------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Day 5**

**Form: Smoking Questionnaire (SQ) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:06**

**Generated On: 20 Jul 2016 11:47:42**

---

Months \_\_\_\_\_

---

Days \_\_\_\_\_

---

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?  
(Please add together any separate periods of quitting)

---

Years \_\_\_\_\_

---

Months \_\_\_\_\_

---

Days \_\_\_\_\_

---

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking?

---

Time

Currently (last 3 months) ☒

---

8. On average, how many Manufactured cigarettes do/did you smoke per day?

---

Manufactured Cigarettes  
per day

12

---

8. On average, how many Hand-rolled Cigarettes do/did you smoke per day?

---

None ☒

---

Hand-rolled Cigarettes  
per day

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Smoking Questionnaire (SQ) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:06**

**Generated On: 20 Jul 2016 11:47:42**

---

8. On average, how many cigars do/did you smoke per  
day?

None ☐

---

Cigars  
per day

---

8. On average, how many pipes do/did you smoke per  
day?

None ☐

---

Pipes  
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Day 5**

**Form: Smoking Questionnaire (SQ) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:06**

**Generated On: 20 Jul 2016 11:47:42**

---

|      |                       |
|------|-----------------------|
| Type | SMOKING QUESTIONNAIRE |
|------|-----------------------|

---

|                               |                           |
|-------------------------------|---------------------------|
| Was paper questionnaire used? | Yes <input type="radio"/> |
|-------------------------------|---------------------------|

---

|                 |       |
|-----------------|-------|
| Reason not done | <hr/> |
|-----------------|-------|

---

|                    |                            |
|--------------------|----------------------------|
| Date of assessment | 21 JAN 2014<br>DD/MMM/YYYY |
|--------------------|----------------------------|

---

|                    |                                 |
|--------------------|---------------------------------|
| Time of assessment | 21:00<br>hour:min 24-hour clock |
|--------------------|---------------------------------|

---

|  |   |
|--|---|
| 1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)? | Daily smoker (at least one cigarette per day, disregarding religious fasting) <input type="radio"/> |
|--|---|

---

|  |                           |
|--|---------------------------|
| 2. Have you ever smoked 100 cigarettes or more in your life? | Yes <input type="radio"/> |
|--|---------------------------|

---

|  |                           |
|--|---------------------------|
| 3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day? | Yes <input type="radio"/> |
|--|---------------------------|

---

|   |          |
|---|----------|
| 4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly? | 25 Years |
|---|----------|

---

|   |  |
|---|--|
| 5. If you are an ex-smoker of cigarettes: For how long have you quit now? |  |
|---|--|

---

|       |       |
|-------|-------|
| Years | <hr/> |
|-------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Smoking Questionnaire (SQ) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:06**

**Generated On: 20 Jul 2016 11:47:42**

---

Months

---

---

Days

---

---

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?  
(Please add together any separate periods of quitting)

---

Years

---

Months

---

Days

---

---

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking?

---

Time

1 year ago ☒

---

8. On average, how many Manufactured cigarettes  
do/did you smoke per day?

---

Manufactured Cigarettes  
per day

12

---

8. On average, how many Hand-rolled Cigarettes do/did  
you smoke per day?

---

None ☒

Hand-rolled Cigarettes  
per day

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Smoking Questionnaire (SQ) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:06**

**Generated On: 20 Jul 2016 11:47:42**

---

8. On average, how many cigars do/did you smoke per  
day?

None ☐

---

Cigars  
per day

---

8. On average, how many pipes do/did you smoke per  
day?

None ☐

---

Pipes  
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Day 5**

**Form: Smoking Questionnaire (SQ) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:06**

**Generated On: 20 Jul 2016 11:47:42**

---

|      |                       |
|------|-----------------------|
| Type | SMOKING QUESTIONNAIRE |
|------|-----------------------|

---

|                               |                           |
|-------------------------------|---------------------------|
| Was paper questionnaire used? | Yes <input type="radio"/> |
|-------------------------------|---------------------------|

---

|                 |       |
|-----------------|-------|
| Reason not done | <hr/> |
|-----------------|-------|

---

|                    |                            |
|--------------------|----------------------------|
| Date of assessment | 21 JAN 2014<br>DD/MMM/YYYY |
|--------------------|----------------------------|

---

|                    |                                 |
|--------------------|---------------------------------|
| Time of assessment | 21:00<br>hour:min 24-hour clock |
|--------------------|---------------------------------|

---

|  |   |
|--|---|
| 1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)? | Daily smoker (at least one cigarette per day, disregarding religious fasting) <input type="radio"/> |
|--|---|

---

|  |                           |
|--|---------------------------|
| 2. Have you ever smoked 100 cigarettes or more in your life? | Yes <input type="radio"/> |
|--|---------------------------|

---

|  |                           |
|--|---------------------------|
| 3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day? | Yes <input type="radio"/> |
|--|---------------------------|

---

|   |          |
|---|----------|
| 4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly? | 25 Years |
|---|----------|

---

|   |  |
|---|--|
| 5. If you are an ex-smoker of cigarettes: For how long have you quit now? |  |
|---|--|

---

|       |       |
|-------|-------|
| Years | <hr/> |
|-------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Smoking Questionnaire (SQ) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:06**

**Generated On: 20 Jul 2016 11:47:42**

---

Months \_\_\_\_\_

---

Days \_\_\_\_\_

---

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?  
(Please add together any separate periods of quitting)

---

Years \_\_\_\_\_

---

Months \_\_\_\_\_

---

Days \_\_\_\_\_

---

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking?

---

Time

5 years ago ☒

---

8. On average, how many Manufactured cigarettes  
do/did you smoke per day?

---

Manufactured Cigarettes  
per day

20

---

8. On average, how many Hand-rolled Cigarettes do/did  
you smoke per day?

---

None ☒

---

Hand-rolled Cigarettes  
per day \_\_\_\_\_

---

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Smoking Questionnaire (SQ) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:06**

**Generated On: 20 Jul 2016 11:47:42**

---

8. On average, how many cigars do/did you smoke per  
day?

None ☐

---

Cigars  
per day

---

8. On average, how many pipes do/did you smoke per  
day?

None ☐

---

Pipes  
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Day 5**

**Form: Smoking Questionnaire (SQ) (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:06**

**Generated On: 20 Jul 2016 11:47:42**

---

|      |                       |
|------|-----------------------|
| Type | SMOKING QUESTIONNAIRE |
|------|-----------------------|

---

|                               |                           |
|-------------------------------|---------------------------|
| Was paper questionnaire used? | Yes <input type="radio"/> |
|-------------------------------|---------------------------|

---

|                 |       |
|-----------------|-------|
| Reason not done | <hr/> |
|-----------------|-------|

---

|                    |                            |
|--------------------|----------------------------|
| Date of assessment | 21 JAN 2014<br>DD/MMM/YYYY |
|--------------------|----------------------------|

---

|                    |                                 |
|--------------------|---------------------------------|
| Time of assessment | 21:00<br>hour:min 24-hour clock |
|--------------------|---------------------------------|

---

|  |   |
|--|---|
| 1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)? | Daily smoker (at least one cigarette per day, disregarding religious fasting) <input type="radio"/> |
|--|---|

---

|  |                           |
|--|---------------------------|
| 2. Have you ever smoked 100 cigarettes or more in your life? | Yes <input type="radio"/> |
|--|---------------------------|

---

|  |                           |
|--|---------------------------|
| 3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day? | Yes <input type="radio"/> |
|--|---------------------------|

---

|   |          |
|---|----------|
| 4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly? | 25 Years |
|---|----------|

---

|   |  |
|---|--|
| 5. If you are an ex-smoker of cigarettes: For how long have you quit now? |  |
|---|--|

---

|       |       |
|-------|-------|
| Years | <hr/> |
|-------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Smoking Questionnaire (SQ) (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:06**

**Generated On: 20 Jul 2016 11:47:42**

---

Months \_\_\_\_\_

---

Days \_\_\_\_\_

---

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?  
(Please add together any separate periods of quitting)

---

Years \_\_\_\_\_

---

Months \_\_\_\_\_

---

Days \_\_\_\_\_

---

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking?

---

Time

10 years ago ☒

---

8. On average, how many Manufactured cigarettes  
do/did you smoke per day?

---

Manufactured Cigarettes  
per day

20

---

8. On average, how many Hand-rolled Cigarettes do/did  
you smoke per day?

---

None ☒

---

Hand-rolled Cigarettes  
per day \_\_\_\_\_

---

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Smoking Questionnaire (SQ) (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:06**

**Generated On: 20 Jul 2016 11:47:42**

---

8. On average, how many cigars do/did you smoke per  
day?

None ☐

---

Cigars  
per day

---

8. On average, how many pipes do/did you smoke per  
day?

None ☐

---

Pipes  
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Day 5**

**Form: Smoking Questionnaire (SQ) (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:06**

**Generated On: 20 Jul 2016 11:47:42**

---

|      |                       |
|------|-----------------------|
| Type | SMOKING QUESTIONNAIRE |
|------|-----------------------|

---

|                               |                           |
|-------------------------------|---------------------------|
| Was paper questionnaire used? | Yes <input type="radio"/> |
|-------------------------------|---------------------------|

---

|                 |       |
|-----------------|-------|
| Reason not done | <hr/> |
|-----------------|-------|

---

|                    |                            |
|--------------------|----------------------------|
| Date of assessment | 21 JAN 2014<br>DD/MMM/YYYY |
|--------------------|----------------------------|

---

|                    |                                 |
|--------------------|---------------------------------|
| Time of assessment | 21:00<br>hour:min 24-hour clock |
|--------------------|---------------------------------|

---

|  |   |
|--|---|
| 1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)? | Daily smoker (at least one cigarette per day, disregarding religious fasting) <input type="radio"/> |
|--|---|

---

|  |                           |
|--|---------------------------|
| 2. Have you ever smoked 100 cigarettes or more in your life? | Yes <input type="radio"/> |
|--|---------------------------|

---

|  |                           |
|--|---------------------------|
| 3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day? | Yes <input type="radio"/> |
|--|---------------------------|

---

|   |          |
|---|----------|
| 4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly? | 25 Years |
|---|----------|

---

|   |  |
|---|--|
| 5. If you are an ex-smoker of cigarettes: For how long have you quit now? |  |
|---|--|

---

|       |       |
|-------|-------|
| Years | <hr/> |
|-------|-------|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Day 5**

**Form: Smoking Questionnaire (SQ) (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:06**

**Generated On: 20 Jul 2016 11:47:42**

---

Months

---

---

Days

---

---

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?  
(Please add together any separate periods of quitting)

---

Years

---

Months

---

Days

---

---

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking?

---

Time

15 years ago ☒

---

8. On average, how many Manufactured cigarettes  
do/did you smoke per day?

---

Manufactured Cigarettes  
per day

20

---

8. On average, how many Hand-rolled Cigarettes do/did  
you smoke per day?

---

None ☒

---

Hand-rolled Cigarettes  
per day

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Smoking Questionnaire (SQ) (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:06**

**Generated On: 20 Jul 2016 11:47:42**

---

8. On average, how many cigars do/did you smoke per  
day?

None ☐

---

Cigars  
per day

---

8. On average, how many pipes do/did you smoke per  
day?

None ☐

---

Pipes  
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Day 5**

**Form: Smoking Questionnaire (SQ) (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:06**

**Generated On: 20 Jul 2016 11:47:42**

---

|      |                       |
|------|-----------------------|
| Type | SMOKING QUESTIONNAIRE |
|------|-----------------------|

---

|                               |                           |
|-------------------------------|---------------------------|
| Was paper questionnaire used? | Yes <input type="radio"/> |
|-------------------------------|---------------------------|

---

|                 |       |
|-----------------|-------|
| Reason not done | <hr/> |
|-----------------|-------|

---

|                    |                            |
|--------------------|----------------------------|
| Date of assessment | 21 JAN 2014<br>DD/MMM/YYYY |
|--------------------|----------------------------|

---

|                    |                                 |
|--------------------|---------------------------------|
| Time of assessment | 21:00<br>hour:min 24-hour clock |
|--------------------|---------------------------------|

---

|  |   |
|--|---|
| 1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)? | Daily smoker (at least one cigarette per day, disregarding religious fasting) <input type="radio"/> |
|--|---|

---

|  |                           |
|--|---------------------------|
| 2. Have you ever smoked 100 cigarettes or more in your life? | Yes <input type="radio"/> |
|--|---------------------------|

---

|  |                           |
|--|---------------------------|
| 3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day? | Yes <input type="radio"/> |
|--|---------------------------|

---

|   |          |
|---|----------|
| 4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly? | 25 Years |
|---|----------|

---

|   |  |
|---|--|
| 5. If you are an ex-smoker of cigarettes: For how long have you quit now? |  |
|---|--|

---

|       |       |
|-------|-------|
| Years | <hr/> |
|-------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Day 5**

**Form: Smoking Questionnaire (SQ) (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:06**

**Generated On: 20 Jul 2016 11:47:42**

---

Months \_\_\_\_\_

---

Days \_\_\_\_\_

---

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?  
(Please add together any separate periods of quitting)

---

Years \_\_\_\_\_

---

Months \_\_\_\_\_

---

Days \_\_\_\_\_

---

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking?

---

Time

20 years ago ☒

---

8. On average, how many Manufactured cigarettes do/did you smoke per day?

---

Manufactured Cigarettes  
per day

20

---

8. On average, how many Hand-rolled Cigarettes do/did you smoke per day?

---

None ☒

---

Hand-rolled Cigarettes  
per day

---

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Smoking Questionnaire (SQ) (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:06**

**Generated On: 20 Jul 2016 11:47:42**

---

8. On average, how many cigars do/did you smoke per  
day?

None ☐

---

Cigars  
per day

---

8. On average, how many pipes do/did you smoke per  
day?

None ☐

---

Pipes  
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Day 5**

**Form: Smoking Questionnaire (SQ) (7)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:06**

**Generated On: 20 Jul 2016 11:47:42**

---

|      |                       |
|------|-----------------------|
| Type | SMOKING QUESTIONNAIRE |
|------|-----------------------|

---

|                               |                           |
|-------------------------------|---------------------------|
| Was paper questionnaire used? | Yes <input type="radio"/> |
|-------------------------------|---------------------------|

---

|                 |       |
|-----------------|-------|
| Reason not done | <hr/> |
|-----------------|-------|

---

|                    |                            |
|--------------------|----------------------------|
| Date of assessment | 21 JAN 2014<br>DD/MMM/YYYY |
|--------------------|----------------------------|

---

|                    |                                 |
|--------------------|---------------------------------|
| Time of assessment | 21:00<br>hour:min 24-hour clock |
|--------------------|---------------------------------|

---

|  |   |
|--|---|
| 1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)? | Daily smoker (at least one cigarette per day, disregarding religious fasting) <input type="radio"/> |
|--|---|

---

|  |                           |
|--|---------------------------|
| 2. Have you ever smoked 100 cigarettes or more in your life? | Yes <input type="radio"/> |
|--|---------------------------|

---

|  |                           |
|--|---------------------------|
| 3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day? | Yes <input type="radio"/> |
|--|---------------------------|

---

|   |          |
|---|----------|
| 4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly? | 25 Years |
|---|----------|

---

|   |  |
|---|--|
| 5. If you are an ex-smoker of cigarettes: For how long have you quit now? |  |
|---|--|

---

|       |       |
|-------|-------|
| Years | <hr/> |
|-------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Smoking Questionnaire (SQ) (7)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:06**

**Generated On: 20 Jul 2016 11:47:42**

---

Months \_\_\_\_\_

---

Days \_\_\_\_\_

---

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?  
(Please add together any separate periods of quitting)

---

Years \_\_\_\_\_

---

Months \_\_\_\_\_

---

Days \_\_\_\_\_

---

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking?

---

Time

More than 20 years ago ☒

---

8. On average, how many Manufactured cigarettes  
do/did you smoke per day?

---

Manufactured Cigarettes  
per day

20

---

8. On average, how many Hand-rolled Cigarettes do/did  
you smoke per day?

---

None ☒

---

Hand-rolled Cigarettes  
per day \_\_\_\_\_

---

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Smoking Questionnaire (SQ) (7)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:06**

**Generated On: 20 Jul 2016 11:47:42**

---

8. On average, how many cigars do/did you smoke per  
day?

None ☐

---

Cigars  
per day

---

8. On average, how many pipes do/did you smoke per  
day?

None ☐

---

Pipes  
per day



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Supplemental Questions**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:11**

**Generated On: 20 Jul 2016 11:47:42**

---

Was paper questionnaire used? Yes ☒

---

Reason not done \_\_\_\_\_

---

Date of Assessment 21 JAN 2014  
DD/MMM/YYYY

---

Time of assessment 21:01

---

1. How long it takes for the subject to complete the SQ 6 minutes

---

Comments (open-end) \_\_\_\_\_

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Supplemental Questions (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:11**

**Generated On: 20 Jul 2016 11:47:42**

---

Was paper questionnaire used? Yes ☐

---

Reason not done \_\_\_\_\_

---

Date of Assessment 21 JAN 2014  
DD/MMM/YYYY

---

Time of assessment 21:01

---

1. How long it takes for the subject to complete the SQ 6 minutes

---

Question 2. Did the SQ capture your smoking behavior completely? ☐

---

Answer Yes ☐

---

Comments (open-end) \_\_\_\_\_

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Supplemental Questions (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:11**

**Generated On: 20 Jul 2016 11:47:42**

---

Was paper questionnaire used? Yes ☐

---

Reason not done \_\_\_\_\_

---

Date of Assessment 21 JAN 2014  
DD/MMM/YYYY

---

Time of assessment 21:01

---

1. How long it takes for the subject to complete the SQ 6 minutes

---

Question 3. Did the SQ capture your smoking behavior correctly? ☐

---

Answer Yes ☐

---

Comments (open-end) \_\_\_\_\_

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Supplemental Questions (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:11**

**Generated On: 20 Jul 2016 11:47:42**

---

Was paper questionnaire used? Yes ☐

---

Reason not done \_\_\_\_\_

---

Date of Assessment 21 JAN 2014  
DD/MMM/YYYY

---

Time of assessment 21:01

---

1. How long it takes for the subject to complete the SQ 6 minutes

---

Question 4. Did the SQ capture your smoking history completely? ☐

---

Answer Yes ☐

---

Comments (open-end) \_\_\_\_\_

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Supplemental Questions (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:11**

**Generated On: 20 Jul 2016 11:47:42**

---

Was paper questionnaire used? Yes ☐

---

Reason not done \_\_\_\_\_

---

Date of Assessment 21 JAN 2014  
DD/MMM/YYYY

---

Time of assessment 21:01

---

1. How long it takes for the subject to complete the SQ 6 minutes

---

Question 5. Did the SQ capture your smoking history correctly? ☐

---

Answer Yes ☐

---

Comments (open-end) \_\_\_\_\_

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Supplemental Questions (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:11**

**Generated On: 20 Jul 2016 11:47:42**

---

Was paper questionnaire used? Yes ☐

---

Reason not done \_\_\_\_\_

---

Date of Assessment 21 JAN 2014  
DD/MMM/YYYY

---

Time of assessment 21:01

---

1. How long it takes for the subject to complete the SQ 6 minutes

---

Question 6. Was the SQ self-explaining? ☐

---

Answer Yes ☐

---

Comments (open-end) \_\_\_\_\_

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Supplemental Questions (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:11**

**Generated On: 20 Jul 2016 11:47:42**

---

Was paper questionnaire used? Yes ☐

---

Reason not done \_\_\_\_\_

---

Date of Assessment 21 JAN 2014  
DD/MMM/YYYY

---

Time of assessment 21:01

---

1. How long it takes for the subject to complete the SQ 6 minutes

---

Question 7. Was the SQ easy to use? ☐

---

Answer Yes ☐

---

Comments (open-end) \_\_\_\_\_

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Questionnaire on smoking urges (QSU)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:14**

**Generated On: 20 Jul 2016 11:47:42**

---

|      |     |
|------|-----|
| Type | QSU |
|------|-----|

---

|               |         |
|---------------|---------|
| Date of Birth | (b) (6) |
|---------------|---------|

---

|                    |             |
|--------------------|-------------|
| Date of assessment | 2014 JAN 21 |
|--------------------|-------------|

DD/MMM/YYYY

---

|                    |       |
|--------------------|-------|
| Time of assessment | 20:10 |
|--------------------|-------|

hour:min 24-hour clock

---

|                   |                                 |
|-------------------|---------------------------------|
| Assessment Status | Completed <input type="radio"/> |
|-------------------|---------------------------------|

---

|  |   |
|--|---|
| 1. I have a desire for a cigarette right now | Somewhat disagree <input type="radio"/> |
|--|---|

---

|   |  |
|---|--|
| 2. Nothing would be better than smoking a cigarette right now | Do not agree or disagree <input type="radio"/> |
|---|--|

---

|   |   |
|---|---|
| 3. If it were possible I would probably smoke now | Somewhat disagree <input type="radio"/> |
|---|---|

---

|   |   |
|---|---|
| 4. I could control things better right now if I could smoke | Strongly disagree <input type="radio"/> |
|---|---|

---

|  |  |
|--|--|
| 5. All I want right now is a cigarette | Do not agree or disagree <input type="radio"/> |
|--|--|

---

|                                   |  |
|-----------------------------------|--|
| 6. I have an urge for a cigarette | Do not agree or disagree <input type="radio"/> |
|-----------------------------------|--|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Questionnaire on smoking urges (QSU)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:14**

**Generated On: 20 Jul 2016 11:47:42**

---

7. A cigarette would taste good now Do not agree or disagree ☐

---

8. I would do almost anything for a cigarette now Disagree ☐

---

9. Smoking would make me less depressed Disagree ☐

---

10. I am going to smoke as soon as possible Somewhat agree ☐

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (CEMA, HPMa, HBMA)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:17**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:17**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112450000096        |
| Analyte                   | HPMA                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 5                     |
| Celerion Study Number     | AA99128-03            |
| Date of Collection        | 2014-JAN-22           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 5                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (CEMA, HPMa, HBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:17**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

6

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:17**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112450000096        |
| Analyte                   | CEMA                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 5                     |
| Celerion Study Number     | AA99128-03            |
| Date of Collection        | 2014-JAN-22           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 5                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:17**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

6

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:17**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112450000096        |
| Analyte                   | HBMA                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 5                     |
| Celerion Study Number     | AA99128-03            |
| Date of Collection        | 2014-JAN-22           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 5                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:17**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

6

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (NNN, NNAL)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:15**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (NNN, NNAL) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:15**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112460000096        |
| Analyte                   | NNAL                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | PG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 5                     |
| Celerion Study Number     | AA99128-04            |
| Date of Collection        | 2014-JAN-22           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 5                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (NNN, NNAL) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:15**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

6

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (NNN, NNAL) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:15**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112460000096        |
| Analyte                   | NNN                   |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | PG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 5                     |
| Celerion Study Number     | AA99128-04            |
| Date of Collection        | 2014-JAN-22           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 5                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (NNN, NNAL) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:15**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

6

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (HEMA)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:15**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (HEMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:15**

**Generated On: 20 Jul 2016 11:47:42**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05112470000096 |
|----------------|----------------|

---

|         |      |
|---------|------|
| Analyte | HEMA |
|---------|------|

---

|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |       |
|------------|-------|
| Lab Status | OTHER |
|------------|-------|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | ANALYSIS NOT REQUIRED |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 5 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-05 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-JAN-22 |
|--------------------|-------------|

---

|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

---

|                 |   |
|-----------------|---|
| Urine Start Day | 5 |
|-----------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (HEMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:15**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

6

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:17**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:17**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112480000063        |
| Analyte                   | COT                   |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 5                     |
| Celerion Study Number     | AA99128-06            |
| Date of Collection        | 2014-JAN-22           |
| Timepoint-minutes         |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:17**

**Generated On: 20 Jul 2016 11:47:42**

---

|                 |   |
|-----------------|---|
| Urine Start Day | 5 |
|-----------------|---|

---

|               |   |
|---------------|---|
| Urine End Day | 6 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:17**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112480000063        |
| Analyte                   | COT-GLUC              |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 5                     |
| Celerion Study Number     | AA99128-06            |
| Date of Collection        | 2014-JAN-22           |
| Timepoint-minutes         |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:17**

**Generated On: 20 Jul 2016 11:47:42**

---

|                 |   |
|-----------------|---|
| Urine Start Day | 5 |
|-----------------|---|

---

|               |   |
|---------------|---|
| Urine End Day | 6 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:17**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112480000063        |
| Analyte                   | NIC                   |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 5                     |
| Celerion Study Number     | AA99128-06            |
| Date of Collection        | 2014-JAN-22           |
| Timepoint-minutes         |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:17**

**Generated On: 20 Jul 2016 11:47:42**

---

|                 |   |
|-----------------|---|
| Urine Start Day | 5 |
|-----------------|---|

---

|               |   |
|---------------|---|
| Urine End Day | 6 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:17**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112480000063        |
| Analyte                   | NIC-GLUC              |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 5                     |
| Celerion Study Number     | AA99128-06            |
| Date of Collection        | 2014-JAN-22           |
| Timepoint-minutes         |                       |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:17**

**Generated On: 20 Jul 2016 11:47:42**

---

|                 |   |
|-----------------|---|
| Urine Start Day | 5 |
|-----------------|---|

---

|               |   |
|---------------|---|
| Urine End Day | 6 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:17**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112480000063        |
| Analyte                   | THCOT                 |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 5                     |
| Celerion Study Number     | AA99128-06            |
| Date of Collection        | 2014-JAN-22           |
| Timepoint-minutes         |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:17**

**Generated On: 20 Jul 2016 11:47:42**

---

|                 |   |
|-----------------|---|
| Urine Start Day | 5 |
|-----------------|---|

---

|               |   |
|---------------|---|
| Urine End Day | 6 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:17**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112480000063        |
| Analyte                   | THCOT-GLUC            |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 5                     |
| Celerion Study Number     | AA99128-06            |
| Date of Collection        | 2014-JAN-22           |
| Timepoint-minutes         |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:17**

**Generated On: 20 Jul 2016 11:47:42**

---

|                 |   |
|-----------------|---|
| Urine Start Day | 5 |
|-----------------|---|

---

|               |   |
|---------------|---|
| Urine End Day | 6 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (3-OH BaP)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:18**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (3-OH BaP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:18**

**Generated On: 20 Jul 2016 11:47:42**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05112490000096 |
|----------------|----------------|

---

|         |          |
|---------|----------|
| Analyte | 3-OH BAP |
|---------|----------|

---

|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | FG/ML |
|-------------|-------|

---

|            |       |
|------------|-------|
| Lab Status | OTHER |
|------------|-------|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | ANALYSIS NOT REQUIRED |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 5 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-07 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-JAN-22 |
|--------------------|-------------|

---

|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

---

|                 |   |
|-----------------|---|
| Urine Start Day | 5 |
|-----------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (3-OH BaP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:18**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

6

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Plasma (Caffeine, Paraxanthine)**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

PLASMA

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Plasma (Caffeine, Paraxanthine) (1)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05112500000026 |
|----------------|----------------|

---

|         |          |
|---------|----------|
| Analyte | CAFFEINE |
|---------|----------|

---

|             |        |
|-------------|--------|
| Sample type | PLASMA |
|-------------|--------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |       |
|------------|-------|
| Lab Status | OTHER |
|------------|-------|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | ANALYSIS NOT REQUIRED |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 6 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 5 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-08 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-JAN-21 |
|--------------------|-------------|

---

|                   |   |
|-------------------|---|
| Timepoint-minutes | 0 |
|-------------------|---|

---

|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Plasma (Caffeine, Paraxanthine) (1)**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

5

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Plasma (Caffeine, Paraxanthine) (2)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05112500000026 |
|----------------|----------------|

---

|         |              |
|---------|--------------|
| Analyte | PARAXANTHINE |
|---------|--------------|

---

|             |        |
|-------------|--------|
| Sample type | PLASMA |
|-------------|--------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |       |
|------------|-------|
| Lab Status | OTHER |
|------------|-------|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | ANALYSIS NOT REQUIRED |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 6 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 5 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-08 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-JAN-21 |
|--------------------|-------------|

---

|                   |   |
|-------------------|---|
| Timepoint-minutes | 0 |
|-------------------|---|

---

|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Plasma (Caffeine, Paraxanthine) (2)**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

5

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:18**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:18**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112510000096        |
| Analyte                   | 1-NA                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | PG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 5                     |
| Celerion Study Number     | AA99128-09            |
| Date of Collection        | 2014-JAN-22           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 5                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:18**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

6

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:18**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112510000096        |
| Analyte                   | 2-NA                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | PG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 5                     |
| Celerion Study Number     | AA99128-09            |
| Date of Collection        | 2014-JAN-22           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 5                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:18**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

6

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:18**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112510000096        |
| Analyte                   | 4-ABP                 |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | PG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 5                     |
| Celerion Study Number     | AA99128-09            |
| Date of Collection        | 2014-JAN-22           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 5                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:18**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

6

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:18**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112510000096        |
| Analyte                   | O-TOL                 |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | PG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 5                     |
| Celerion Study Number     | AA99128-09            |
| Date of Collection        | 2014-JAN-22           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 5                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:18**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

---

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (11-dTXb2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:15**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (11-dTXb2) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:15**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112530000060        |
| Analyte                   | 11-DTXB2              |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | PG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 5                     |
| Celerion Study Number     | AA99128-11            |
| Date of Collection        | 2014-JAN-22           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 5                     |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (11-dTXb2) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:15**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

6

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (iPF2a-III)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:15**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (iPF2a-III) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:15**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112540000060        |
| Analyte                   | IPF2A-III             |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | PG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 5                     |
| Celerion Study Number     | AA99128-12            |
| Date of Collection        | 2014-JAN-22           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 5                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (iPF2a-III) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:15**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

6

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (Ames)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:18**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (Ames) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:18**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05113320000023        |
| Analyte                   | AMES                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | REV/ML                |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | COUNT                 |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 5                     |
| Celerion Study Number     | AA99128-15            |
| Date of Collection        | 2014-JAN-22           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 5                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (Ames) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:18**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

6

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (1-OHP)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:18**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (1-OHP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:18**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05115190001185        |
| Analyte                   | 1-OHP                 |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | PG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 5                     |
| Celerion Study Number     | AA99598-03            |
| Date of Collection        | 2014-JAN-22           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 5                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (1-OHP) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:18**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

6

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (SPMA, SBMA)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:15**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (SPMA, SBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:15**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05115170000096        |
| Analyte                   | SBMA                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 5                     |
| Celerion Study Number     | AA99598-01            |
| Date of Collection        | 2014-JAN-22           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 5                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (SPMA, SBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:15**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

6

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (SPMA, SBMA) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:15**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05115170000096        |
| Analyte                   | SPMA                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 5                     |
| Celerion Study Number     | AA99598-01            |
| Date of Collection        | 2014-JAN-22           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 5                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (SPMA, SBMA) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:15**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

6

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (MHBMA)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:15**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (MHBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:15**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05115180000096        |
| Analyte                   | MHBMA                 |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 5                     |
| Celerion Study Number     | AA99598-02            |
| Date of Collection        | 2014-JAN-22           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 5                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (MHBMA) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:15**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

6

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (Creatinine)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:18**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (Creatinine) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:18**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05115160000096        |
| Analyte                   | CREATININE            |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | MG/DL                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | SPECTROPHOTOMETRIC    |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 5                     |
| Celerion Study Number     | AA99128-14            |
| Date of Collection        | 2014-JAN-22           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 5                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Urine (Creatinine) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:18**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

6

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:16**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

PLASMA

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:16**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112430000101        |
| Analyte                   | COT                   |
| Sample type               | PLASMA                |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 5                     |
| Celerion Study Number     | AA99128-01            |
| Date of Collection        | 2014-JAN-21           |
| Timepoint-minutes         | -15                   |
| Urine Start Day           |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:16**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

5

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:16**

**Generated On: 20 Jul 2016 11:47:42**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05112430000101 |
|----------------|----------------|

---

|         |     |
|---------|-----|
| Analyte | NIC |
|---------|-----|

---

|             |        |
|-------------|--------|
| Sample type | PLASMA |
|-------------|--------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |       |
|------------|-------|
| Lab Status | OTHER |
|------------|-------|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | ANALYSIS NOT REQUIRED |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 5 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-01 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-JAN-21 |
|--------------------|-------------|

---

|                   |     |
|-------------------|-----|
| Timepoint-minutes | -15 |
|-------------------|-----|

---

|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

---

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:16**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

5

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:16**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112430000102        |
| Analyte                   | COT                   |
| Sample type               | PLASMA                |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 2                     |
| Day of Visit              | 5                     |
| Celerion Study Number     | AA99128-01            |
| Date of Collection        | 2014-JAN-21           |
| Timepoint-minutes         | 0                     |
| Urine Start Day           |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:16**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

5

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:16**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112430000102        |
| Analyte                   | NIC                   |
| Sample type               | PLASMA                |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 2                     |
| Day of Visit              | 5                     |
| Celerion Study Number     | AA99128-01            |
| Date of Collection        | 2014-JAN-21           |
| Timepoint-minutes         | 0                     |
| Urine Start Day           |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:16**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

5

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:16**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112430000103        |
| Analyte                   | COT                   |
| Sample type               | PLASMA                |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 4                     |
| Day of Visit              | 5                     |
| Celerion Study Number     | AA99128-01            |
| Date of Collection        | 2014-JAN-21           |
| Timepoint-minutes         | 0                     |
| Urine Start Day           |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:16**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

5

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:16**

**Generated On: 20 Jul 2016 11:47:42**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05112430000103 |
|----------------|----------------|

---

|         |     |
|---------|-----|
| Analyte | NIC |
|---------|-----|

---

|             |        |
|-------------|--------|
| Sample type | PLASMA |
|-------------|--------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |       |
|------------|-------|
| Lab Status | OTHER |
|------------|-------|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | ANALYSIS NOT REQUIRED |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 4 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 5 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-01 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-JAN-21 |
|--------------------|-------------|

---

|                   |   |
|-------------------|---|
| Timepoint-minutes | 0 |
|-------------------|---|

---

|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

---

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:16**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

5

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (7)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:16**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112430000104        |
| Analyte                   | COT                   |
| Sample type               | PLASMA                |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 6                     |
| Day of Visit              | 5                     |
| Celerion Study Number     | AA99128-01            |
| Date of Collection        | 2014-JAN-21           |
| Timepoint-minutes         | 0                     |
| Urine Start Day           |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (7)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:16**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

5

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (8)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:16**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112430000104        |
| Analyte                   | NIC                   |
| Sample type               | PLASMA                |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 6                     |
| Day of Visit              | 5                     |
| Celerion Study Number     | AA99128-01            |
| Date of Collection        | 2014-JAN-21           |
| Timepoint-minutes         | 0                     |
| Urine Start Day           |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (8)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:16**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

5

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (9)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:16**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112430000105        |
| Analyte                   | COT                   |
| Sample type               | PLASMA                |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 8                     |
| Day of Visit              | 5                     |
| Celerion Study Number     | AA99128-01            |
| Date of Collection        | 2014-JAN-21           |
| Timepoint-minutes         | 0                     |
| Urine Start Day           |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (9)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:16**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

5

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (10)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:16**

**Generated On: 20 Jul 2016 11:47:42**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05112430000105 |
|----------------|----------------|

---

|         |     |
|---------|-----|
| Analyte | NIC |
|---------|-----|

---

|             |        |
|-------------|--------|
| Sample type | PLASMA |
|-------------|--------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |       |
|------------|-------|
| Lab Status | OTHER |
|------------|-------|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | ANALYSIS NOT REQUIRED |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 8 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 5 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-01 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-JAN-21 |
|--------------------|-------------|

---

|                   |   |
|-------------------|---|
| Timepoint-minutes | 0 |
|-------------------|---|

---

|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

---

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (10)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:16**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

5

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (11)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:16**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112430000106        |
| Analyte                   | COT                   |
| Sample type               | PLASMA                |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 10                    |
| Day of Visit              | 5                     |
| Celerion Study Number     | AA99128-01            |
| Date of Collection        | 2014-JAN-21           |
| Timepoint-minutes         | 0                     |
| Urine Start Day           |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (11)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:16**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

5

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (12)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:16**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112430000106        |
| Analyte                   | NIC                   |
| Sample type               | PLASMA                |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 10                    |
| Day of Visit              | 5                     |
| Celerion Study Number     | AA99128-01            |
| Date of Collection        | 2014-JAN-21           |
| Timepoint-minutes         | 0                     |
| Urine Start Day           |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (12)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:16**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

5

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (13)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:16**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112430000107        |
| Analyte                   | COT                   |
| Sample type               | PLASMA                |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 12                    |
| Day of Visit              | 5                     |
| Celerion Study Number     | AA99128-01            |
| Date of Collection        | 2014-JAN-21           |
| Timepoint-minutes         | 0                     |
| Urine Start Day           |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (13)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:16**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

5

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (14)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:16**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112430000107        |
| Analyte                   | NIC                   |
| Sample type               | PLASMA                |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 12                    |
| Day of Visit              | 5                     |
| Celerion Study Number     | AA99128-01            |
| Date of Collection        | 2014-JAN-21           |
| Timepoint-minutes         | 0                     |
| Urine Start Day           |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (14)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:16**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

5

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (15)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:16**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112430000108        |
| Analyte                   | COT                   |
| Sample type               | PLASMA                |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 14                    |
| Day of Visit              | 5                     |
| Celerion Study Number     | AA99128-01            |
| Date of Collection        | 2014-JAN-21           |
| Timepoint-minutes         | 0                     |
| Urine Start Day           |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (15)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:16**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

5

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (16)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:16**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112430000108        |
| Analyte                   | NIC                   |
| Sample type               | PLASMA                |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 14                    |
| Day of Visit              | 5                     |
| Celerion Study Number     | AA99128-01            |
| Date of Collection        | 2014-JAN-21           |
| Timepoint-minutes         | 0                     |
| Urine Start Day           |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (16)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:16**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

5

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (17)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:16**

**Generated On: 20 Jul 2016 11:47:42**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05112430000109 |
|----------------|----------------|

---

|         |     |
|---------|-----|
| Analyte | COT |
|---------|-----|

---

|             |        |
|-------------|--------|
| Sample type | PLASMA |
|-------------|--------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |       |
|------------|-------|
| Lab Status | OTHER |
|------------|-------|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | ANALYSIS NOT REQUIRED |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |    |
|---------------------------|----|
| Planned time point (Hour) | 16 |
|---------------------------|----|

---

|              |   |
|--------------|---|
| Day of Visit | 5 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-01 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-JAN-21 |
|--------------------|-------------|

---

|                   |   |
|-------------------|---|
| Timepoint-minutes | 0 |
|-------------------|---|

---

|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

---

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (17)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:16**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

5

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (18)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:16**

**Generated On: 20 Jul 2016 11:47:42**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05112430000109        |
| Analyte                   | NIC                   |
| Sample type               | PLASMA                |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OTHER                 |
| Sample comment            | ANALYSIS NOT REQUIRED |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 16                    |
| Day of Visit              | 5                     |
| Celerion Study Number     | AA99128-01            |
| Date of Collection        | 2014-JAN-21           |
| Timepoint-minutes         | 0                     |
| Urine Start Day           |                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (18)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:16**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

5

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 6**

**Form: Date of Visit**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:19**

**Generated On: 20 Jul 2016 11:47:42**

---

Date of Visit

22 JAN 2014  
DD/MMM/YYYY

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 6**

**Form: Plasma Nicotine Samples <Day 6> (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:19**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 22 JAN 2014 |
|---------------------|-------------|

---

|                |   |
|----------------|---|
| Scheduled Time | T0 + 20H <input checked="" type="radio"/> |
|----------------|---|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 02:46 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 6**

**Form: Plasma Nicotine Samples <Day 6> (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:19**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 22 JAN 2014 |
|---------------------|-------------|

---

|                |   |
|----------------|---|
| Scheduled Time | T0 + 24H <input checked="" type="radio"/> |
|----------------|---|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 06:56 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 6**

**Form: Plasma Cotinine Samples <Day 6> (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:19**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 22 JAN 2014 |
|---------------------|-------------|

---

|                |   |
|----------------|---|
| Scheduled Time | T0 + 20H <input checked="" type="radio"/> |
|----------------|---|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 02:46 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 6**

**Form: Plasma Cotinine Samples <Day 6> (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:19**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 22 JAN 2014 |
|---------------------|-------------|

---

|                |   |
|----------------|---|
| Scheduled Time | T0 + 24H <input checked="" type="radio"/> |
|----------------|---|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 06:56 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 6**

**Form: CoHb Blood Sample <prior to gas transfer and product>**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:19**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 22 JAN 2014 |
|---------------------|-------------|

---

|           |  |
|-----------|--|
| Timepoint | Prior to gas transfer<br>assessment and prior to<br>product use <input checked="" type="radio"/> |
|-----------|--|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 06:56 |
|--------------------------------|-------|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 6**

**Form: Oxysterols**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:19**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|  |                                      |
|--|--------------------------------------|
| Was the subject fasting for at least 10 hours at time of<br>sample collection? | Yes <input checked="" type="radio"/> |
|--|--------------------------------------|

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 22 JAN 2014 |
|---------------------|-------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 06:56 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Day 6**

**Form: CYP2A6 activity Sample**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:19**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

| Date of sample collection<br>DD/MMM/YYYY | Time of sample collection<br>hour:min 24-hour clock | Parameter                |
|--|---|--------------------------|
| 22 JAN 2014                              | 06:56   | trans-3'-hydroxycotinine |
| 22 JAN 2014                              | 06:56   | cotinine                 |

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 6**

**Form: Risk Marker: sICAM-1**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:19**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 22 JAN 2014 |
|---------------------|-------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 06:56 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Day 6**

**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:19**

**Generated On: 20 Jul 2016 11:47:42**

---

Date of Birth

(b) (6)

---

Date of assessment  
DD/MMM/YYYY

2014 JAN 22  
DD/MMM/YYYY

---

Time of assessment

06:21  
hour:min 24-hour clock

---

Assessment Status

Completed ☒

---

Please indicate for each of the items below, how you have been feeling over the past 24 hours

---

How have you been feeling over the past 24 hours?

None ☐

1. Angry, irritable, frustrated

---

How have you been feeling over the past 24 hours?

None ☐

2. Anxious, nervous

---

How have you been feeling over the past 24 hours?

None ☐

3. Depressed Mood, sad

---

How have you been feeling over the past 24 hours?

Moderate ☐

4. Desire or craving to smoke

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 6**

**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:19**

**Generated On: 20 Jul 2016 11:47:42**

---

How have you been feeling over the past 24 hours? None ☐

5. Difficulty concentrating

---

How have you been feeling over the past 24 hours? Mild ☐

6. Increased appetite, hungry, weight gain

---

How have you been feeling over the past 24 hours? Slight ☐

7. Insomnia, sleep problems, awakening at night

---

How have you been feeling over the past 24 hours? Slight ☐

8. Restless

---

How have you been feeling over the past 24 hours? None ☐

9. Impatient

---

How have you been feeling over the past 24 hours? Slight ☐

10. Constipation

---

How have you been feeling over the past 24 hours? None ☐

11. Dizziness

---

How have you been feeling over the past 24 hours? None ☐

12. Coughing

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 6**

**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:19**

**Generated On: 20 Jul 2016 11:47:42**

---

How have you been feeling over the past 24 hours?

None ☐

13. Dreaming or nightmares

---

How have you been feeling over the past 24 hours?

None ☐

14. Nausea

---

How have you been feeling over the past 24 hours?

None ☐

15. Sore Throat

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 6**

**Form: Cough Assessment**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:20**

**Generated On: 20 Jul 2016 11:47:42**

---

|               |         |
|---------------|---------|
| Date of Birth | (b) (6) |
|---------------|---------|

---

---

|                                   |                            |
|-----------------------------------|----------------------------|
| Date of assessment<br>DD/MMM/YYYY | 2014 JAN 22<br>DD/MMM/YYYY |
|-----------------------------------|----------------------------|

---

---

|                    |                                 |
|--------------------|---------------------------------|
| Time of assessment | 06:18<br>hour:min 24-hour clock |
|--------------------|---------------------------------|

---

---

|                   |  |
|-------------------|--|
| Assessment Status | Completed <input checked="" type="radio"/> |
|-------------------|--|

---

---

|   |                                     |
|---|-------------------------------------|
| Have you experienced a regular need to cough e.g.<br>coughing several times in the last 24 hrs? | No <input checked="" type="radio"/> |
|---|-------------------------------------|

---

If YES, please answer the following questions:

---

---

|   |    |
|---|----|
| First Question: Cough Impact Scale<br>How much is your cough bothering you? | -9 |
|---|----|

---

---

|   |   |
|---|---|
| Second Question: Cough Intensity Scale:<br>How intense is your cough? | Not Applicable <input checked="" type="radio"/> |
|---|---|

---

---

|   |   |
|---|---|
| Third Question: Cough Frequency Scale:<br>How frequently do you normally have to cough each<br>day? | Not Applicable <input checked="" type="radio"/> |
|---|---|

---

---

|   |   |
|---|---|
| Fourth Question: Sputum Production<br>To what extent do you produce sputum when coughing? | Not Applicable <input checked="" type="radio"/> |
|---|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 6**

**Form: Lab\_BU\_COHB (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:21**

**Generated On: 20 Jul 2016 11:47:42**

|                               |                       |
|-------------------------------|-----------------------|
| Sample Barcode                | 05115150000108        |
| Analyte                       | CARBOXYHEMOGLOBIN     |
| Sample type                   | BLOOD                 |
| Result                        | .                     |
| Result Unit                   | %                     |
| Lab Status                    | OTHER                 |
| Sample comment                | ANALYSIS NOT REQUIRED |
| Detection method              | SPECTROPHOTOMETRIC    |
| Lower limit of quantification | 0.500                 |
| Planned time point (Hour)     | 6                     |
| Day of Visit                  | 6                     |
| Celerion Study Number         | AA99128-16            |
| Date of Collection            | 2014-JAN-22           |
| Timepoint-minutes             |                       |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 6**

**Form: Lab\_BU\_COHB (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:21**

**Generated On: 20 Jul 2016 11:47:42**

---

Start Day (24 hour urine only)

---

End Day (24 hour Urine Only)

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 6**

**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:20**

**Generated On: 20 Jul 2016 11:47:42**

|  |                                 |
|--|---------------------------------|
| Date of Birth  | (b) (6)                         |
| Date of assessment<br>DD/MMM/YYYY                        | 2014 JAN 22<br>DD/MMM/YYYY      |
| Time of assessment                                       | 06:22<br>hour:min 24-hour clock |
| Assessment Status  | Completed                       |
| 1. Was smoking satisfying?                               | Moderately                      |
| 2. Did cigarettes taste good?                            | Moderately                      |
| 3. Did you enjoy the sensation in your throat and chest? | Little                          |
| 4. Did smoking calm you down?                            | Moderately                      |
| 5. Did smoking make you feel more awake?                 | Moderately                      |
| 6. Did smoking make you feel less irritable?             | Little                          |
| 7. Did smoking help you concentrate?                     | Not at all                      |
| 8. Did smoking reduce your hunger for food?              | Little                          |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 6**

**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:20**

**Generated On: 20 Jul 2016 11:47:42**

---

9. Did smoking make you dizzy? Very little ☐

---

10. Did smoking make you nauseous? Not at all ☐

---

11. Did smoking immediately relieve your craving for a  
cigarette? Moderately ☐

---

12. Did you enjoy smoking? Moderately ☐

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 6**

**Form: Questionnaire on smoking urges (QSU)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:19**

**Generated On: 20 Jul 2016 11:47:42**

---

|      |     |
|------|-----|
| Type | QSU |
|------|-----|

---

|               |         |
|---------------|---------|
| Date of Birth | (b) (6) |
|---------------|---------|

---

|                    |             |
|--------------------|-------------|
| Date of assessment | 2014 JAN 22 |
|--------------------|-------------|

DD/MMM/YYYY

---

|                    |       |
|--------------------|-------|
| Time of assessment | 06:23 |
|--------------------|-------|

hour:min 24-hour clock

---

|                   |                                 |
|-------------------|---------------------------------|
| Assessment Status | Completed <input type="radio"/> |
|-------------------|---------------------------------|

---

|  |                             |
|--|-----------------------------|
| 1. I have a desire for a cigarette right now | Agree <input type="radio"/> |
|--|-----------------------------|

---

|  |                             |
|--|-----------------------------|
| 2. Nothing would be better than smoking a cigarette<br>right now | Agree <input type="radio"/> |
|--|-----------------------------|

---

|   |                             |
|---|-----------------------------|
| 3. If it were possible I would probably smoke now | Agree <input type="radio"/> |
|---|-----------------------------|

---

|   |                                |
|---|--------------------------------|
| 4. I could control things better right now if I could smoke | Disagree <input type="radio"/> |
|---|--------------------------------|

---

|  |                             |
|--|-----------------------------|
| 5. All I want right now is a cigarette | Agree <input type="radio"/> |
|--|-----------------------------|

---

|                                   |                             |
|-----------------------------------|-----------------------------|
| 6. I have an urge for a cigarette | Agree <input type="radio"/> |
|-----------------------------------|-----------------------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 6**

**Form: Questionnaire on smoking urges (QSU)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:19**

**Generated On: 20 Jul 2016 11:47:42**

---

7. A cigarette would taste good now Agree ☐

---

8. I would do almost anything for a cigarette now Somewhat agree ☐

---

9. Smoking would make me less depressed Strongly disagree ☐

---

10. I am going to smoke as soon as possible Agree ☐

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 6**

**Form: Risk Markers(CCLS) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:20**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

---

|                      |      |
|----------------------|------|
| Subject ID or Number | 1042 |
|----------------------|------|

---

|             |   |
|-------------|---|
| Subject Sex | F |
|-------------|---|

---

|                       |         |
|-----------------------|---------|
| Subject Date of Birth | (b) (6) |
|-----------------------|---------|

---

|            |      |
|------------|------|
| Visit Name | DAY6 |
|------------|------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | V225843 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 01 22 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:56 |
|------------------------|-------|

---

|                    |  |
|--------------------|--|
| Specimen Condition |  |
|--------------------|--|

---

|            |        |
|------------|--------|
| Battery ID | IM2293 |
|------------|--------|

---

|              |         |
|--------------|---------|
| Battery Name | SICAM-1 |
|--------------|---------|

---

|             |         |
|-------------|---------|
| Lab Test ID | IMT1768 |
|-------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 6**

**Form: Risk Markers(CCLS) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:20**

**Generated On: 20 Jul 2016 11:47:42**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | SICAM-1-RUO                           |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 417.4                                 |
| Reported Numeric Result           | 417.4                                 |
| Reference Range low               | 98.8                                  |
| Reference Range high              | 320.0                                 |
| Range Units                       | NG/ML                                 |
| Conventional Text Result          |                                       |
| Conventional Numeric Result       |                                       |
| Conventional Reference Range Low  |                                       |
| Conventional Reference Range High |                                       |
| Conventional Units                |                                       |
| SI Text Result                    |                                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 6**

**Form: Risk Markers(CCLS) (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:20**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---


SI Units

---

Reported Result Type

---

Alert Flag

High 



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 6**

**Form: Biomarker-Plasma (Nic, Cot, tHCot)**

**Generated On: 20 Jul 2016 11:47:42**

---

Sample type

PLASMA

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 6**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05112430000110 |
|----------------|----------------|

---

|         |     |
|---------|-----|
| Analyte | COT |
|---------|-----|

---

|             |        |
|-------------|--------|
| Sample type | PLASMA |
|-------------|--------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |       |
|------------|-------|
| Lab Status | OTHER |
|------------|-------|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | ANALYSIS NOT REQUIRED |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |    |
|---------------------------|----|
| Planned time point (Hour) | 20 |
|---------------------------|----|

---

|              |   |
|--------------|---|
| Day of Visit | 6 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-01 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-JAN-22 |
|--------------------|-------------|

---

|                   |   |
|-------------------|---|
| Timepoint-minutes | 0 |
|-------------------|---|

---

|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 6**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

5

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 6**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05112430000110 |
|----------------|----------------|

---

|         |     |
|---------|-----|
| Analyte | NIC |
|---------|-----|

---

|             |        |
|-------------|--------|
| Sample type | PLASMA |
|-------------|--------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |       |
|------------|-------|
| Lab Status | OTHER |
|------------|-------|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | ANALYSIS NOT REQUIRED |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |    |
|---------------------------|----|
| Planned time point (Hour) | 20 |
|---------------------------|----|

---

|              |   |
|--------------|---|
| Day of Visit | 6 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-01 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-JAN-22 |
|--------------------|-------------|

---

|                   |   |
|-------------------|---|
| Timepoint-minutes | 0 |
|-------------------|---|

---

|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 6**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

5

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 6**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05112430000111 |
|----------------|----------------|

---

|         |     |
|---------|-----|
| Analyte | COT |
|---------|-----|

---

|             |        |
|-------------|--------|
| Sample type | PLASMA |
|-------------|--------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |       |
|------------|-------|
| Lab Status | OTHER |
|------------|-------|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | ANALYSIS NOT REQUIRED |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |    |
|---------------------------|----|
| Planned time point (Hour) | 24 |
|---------------------------|----|

---

|              |   |
|--------------|---|
| Day of Visit | 6 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-01 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-JAN-22 |
|--------------------|-------------|

---

|                   |   |
|-------------------|---|
| Timepoint-minutes | 0 |
|-------------------|---|

---

|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 6**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

5

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 6**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05112430000111 |
|----------------|----------------|

---

|         |     |
|---------|-----|
| Analyte | NIC |
|---------|-----|

---

|             |        |
|-------------|--------|
| Sample type | PLASMA |
|-------------|--------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |       |
|------------|-------|
| Lab Status | OTHER |
|------------|-------|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | ANALYSIS NOT REQUIRED |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |    |
|---------------------------|----|
| Planned time point (Hour) | 24 |
|---------------------------|----|

---

|              |   |
|--------------|---|
| Day of Visit | 6 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-01 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-JAN-22 |
|--------------------|-------------|

---

|                   |   |
|-------------------|---|
| Timepoint-minutes | 0 |
|-------------------|---|

---

|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 6**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

5

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 6**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (5)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05112520000026 |
|----------------|----------------|

---

|         |     |
|---------|-----|
| Analyte | COT |
|---------|-----|

---

|             |        |
|-------------|--------|
| Sample type | PLASMA |
|-------------|--------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |       |
|------------|-------|
| Lab Status | OTHER |
|------------|-------|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | ANALYSIS NOT REQUIRED |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 6 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-10 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-JAN-22 |
|--------------------|-------------|

---

|                   |   |
|-------------------|---|
| Timepoint-minutes | 0 |
|-------------------|---|

---

|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 6**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (5)**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

6

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 6**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (6)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05112520000026 |
|----------------|----------------|

---

|         |       |
|---------|-------|
| Analyte | THCOT |
|---------|-------|

---

|             |        |
|-------------|--------|
| Sample type | PLASMA |
|-------------|--------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |       |
|------------|-------|
| Lab Status | OTHER |
|------------|-------|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | ANALYSIS NOT REQUIRED |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 6 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-10 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-JAN-22 |
|--------------------|-------------|

---

|                   |   |
|-------------------|---|
| Timepoint-minutes | 0 |
|-------------------|---|

---

|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Day 6**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (6)**

**Generated On: 20 Jul 2016 11:47:42**

---

Urine End Day

6

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Date of Discharge**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:23**

**Generated On: 20 Jul 2016 11:47:42**

---

|               |                            |
|---------------|----------------------------|
| Date of Visit | 22 JAN 2014<br>DD/MMM/YYYY |
|---------------|----------------------------|

---

|                |                                 |
|----------------|---------------------------------|
| Discharge Time | 13:00<br>hour:min 24-hour clock |
|----------------|---------------------------------|

---

|   |                           |
|---|---------------------------|
| Is the subject continuing in the ambulatory period? | Yes <input type="radio"/> |
|---|---------------------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Vital Signs**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:23**

**Generated On: 20 Jul 2016 11:47:42**

---

Were Vitals Signs assessed?

Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

Has the subject smoked within 15 minutes prior to  
assessment

No ☒

---

Time of assessment

10:35  
hour:min 24-hour clock

---

Pulse rate

81  
beats per minute

---

Respiratory rate

16  
breaths per minute

---

Blood Pressure (systolic)

116  
mmHg

---

Blood Pressure (diastolic)

77  
mmHg

---

Vital Signs Position of Subject

Supine ☒

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Advice on the risk of smoking and debriefing**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:23**

**Generated On: 20 Jul 2016 11:47:42**

---

Has the subject received advices on the risks of  
smoking?

Yes ☒

---

Has a debriefing been performed about THS 2.2?

Yes ☒

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Physical Examination**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:21**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed?

Yes ☒

---

If No, please specify the reason:

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Physical Examination (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:21**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed? Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

System General Appearance ☒

---

Outcome Normal ☒

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done False

---

Not Done; please specify the reason: \_\_\_\_\_

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Physical Examination (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:21**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed? Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

System HEENT ☒  
(head, eyes, ears, nose,  
throat)

---

Outcome Normal ☒

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done False

---

Not Done; please specify the reason: \_\_\_\_\_

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Physical Examination (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:21**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed? Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

System Thyroid Gland ☒

---

Outcome Normal ☒

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done False

---

Not Done; please specify the reason: \_\_\_\_\_

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Physical Examination (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:21**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed? Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

System Heart ☒

---

Outcome Normal ☒

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done False

---

Not Done; please specify the reason: \_\_\_\_\_

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Physical Examination (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:21**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed? Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

System Chest ☒

---

Outcome Normal ☒

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done False

---

Not Done; please specify the reason: \_\_\_\_\_

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Physical Examination (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:21**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed? Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

System Lungs ☒

---

Outcome Normal ☒

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done False

---

Not Done; please specify the reason: \_\_\_\_\_

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Physical Examination (7)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:21**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed? Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

System Gastrointestinal ☒

---

Outcome Normal ☒

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done False

---

Not Done; please specify the reason: \_\_\_\_\_



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Physical Examination (8)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:21**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed? Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

System Cardiovascular System ☒

---

Outcome Normal ☒

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done False

---

Not Done; please specify the reason: \_\_\_\_\_

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Physical Examination (9)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:21**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed? Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

System Neurologic ☒

---

Outcome Normal ☒

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done False

---

Not Done; please specify the reason: \_\_\_\_\_

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Physical Examination (10)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:21**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed? Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

System Skin ☒

---

Outcome Normal ☒

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done False

---

Not Done; please specify the reason: \_\_\_\_\_

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Physical Examination (11)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:21**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed? Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

System Back ☒

---

Outcome Normal ☒

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done False

---

Not Done; please specify the reason: \_\_\_\_\_

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Physical Examination (12)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:21**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed? Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

System Musculoskeletal ☒

---

Outcome Normal ☒

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done False

---

Not Done; please specify the reason: \_\_\_\_\_

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Physical Examination (13)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:21**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed? Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

System Abdomen ☒

---

Outcome Normal ☒

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done False

---

Not Done; please specify the reason: \_\_\_\_\_

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Physical Examination (14)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:21**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed? Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

System Dentition ☒

---

Outcome Normal ☒

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done False

---

Not Done; please specify the reason: \_\_\_\_\_

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Physical Examination (15)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:21**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed?

Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

System

Other ☒

---

Other, Specify \_\_\_\_\_

---

Outcome \_\_\_\_\_

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done

True

---

Not Done; please specify the reason: \_\_\_\_\_

NOT EXAMINED



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Physical Examination (16)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:21**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed?

Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

System

Other ☒

---

Other, Specify \_\_\_\_\_

---

Outcome \_\_\_\_\_

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done

True

---

Not Done; please specify the reason: \_\_\_\_\_

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Physical Examination (17)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:21**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed?

Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

System

Other ☒

---

Other, Specify \_\_\_\_\_

---

Outcome \_\_\_\_\_

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done

True

---

Not Done; please specify the reason: \_\_\_\_\_

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Physical Examination (18)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:21**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed?

Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

System

Other ☒

---

Other, Specify \_\_\_\_\_

---

Outcome \_\_\_\_\_

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done

True

---

Not Done; please specify the reason: \_\_\_\_\_

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Physical Examination (19)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:21**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the physical examination performed?

Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

System

Other ☒

---

Other, Specify \_\_\_\_\_

---

Outcome \_\_\_\_\_

---

Abnormal, please specify \_\_\_\_\_

---

Clinically significant \_\_\_\_\_

---

Not Done

True

---

Not Done; please specify the reason: \_\_\_\_\_

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Weight**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:23**

**Generated On: 20 Jul 2016 11:47:42**

---

Measurement(s) assessed?

Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

Date of Assessment

22 JAN 2014  
DD/MMM/YYYY

---

Time of assessment

11:58  
hour:min 24-hour clock

---

Weight

66.7  
kg

---

BMI

24.1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: ECG (12-Lead Standard)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:21**

**Generated On: 20 Jul 2016 11:47:42**

---

Was the ECG performed? Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

Position Supine ☒

---

Heart Rate 87  
beats per minute

---

QRS Interval 71  
msec

---

QT Interval 369  
msec

---

QTcB Interval 446  
msec

---

PR Interval 131  
msec

---

QTcF Interval 419  
msec

---

Interpretation Normal ☒

---

If Abnormal, Clinical Significance \_\_\_\_\_

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: ECG (12-Lead Standard)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:21**

**Generated On: 20 Jul 2016 11:47:42**

---

If Not Clinically significant or clinically Significant, Please  
specify the finding(s)

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Haematology**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:21**

**Generated On: 20 Jul 2016 11:47:42**

---

Were samples collected?

Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

Was the subject fasting for at least 10 hours at time of  
sample collection?

Yes ☒

---

Please document clinically relevant abnormalities in the AE form

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Clinical Chemistry**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:21**

**Generated On: 20 Jul 2016 11:47:42**

---

Were samples collected?

Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

Was the subject fasting for at least 10 hours at time of  
sample collection?

Yes ☒

---

Please document clinically relevant abnormalities in the AE form

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Urine analysis**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:21**

**Generated On: 20 Jul 2016 11:47:42**

---

Were samples collected?

Yes ☒

---

If No, please specify the reason: \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Urine Pregnancy Test**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:23**

**Generated On: 20 Jul 2016 11:47:42**

---

|          |       |
|----------|-------|
| Not Done | False |
|----------|-------|

---

|                             |       |
|-----------------------------|-------|
| If Not Done, specify reason | <hr/> |
|-----------------------------|-------|

---

|              |                            |
|--------------|----------------------------|
| Date of Test | 22 JAN 2014<br>DD/MMM/YYYY |
|--------------|----------------------------|

---

|              |                                 |
|--------------|---------------------------------|
| Time of Test | 09:09<br>hour:min 24-hour clock |
|--------------|---------------------------------|

---

|                |   |
|----------------|---|
| Specify result | Negative <input checked="" type="radio"/> |
|----------------|---|

---

|  |       |
|--|-------|
| If unclear, please confirm with FSH test | <hr/> |
|--|-------|

---

|                            |       |
|----------------------------|-------|
| Specify result of FSH test | <hr/> |
|----------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: CO Breath Test**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:21**

**Generated On: 20 Jul 2016 11:47:42**

---

|                     |       |
|---------------------|-------|
| Assessment not done | False |
|---------------------|-------|

---

If Not Done, please specify the reason: \_\_\_\_\_

---

|                           |                        |
|---------------------------|------------------------|
| Actual Time of Assessment | 10:43                  |
|                           | hour:min 24-hour clock |

---

|        |     |
|--------|-----|
| Result | 8   |
|        | ppm |

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (1)**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☐

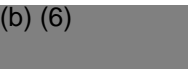
---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6) 

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225843

---

Actual Collection Date 2014 01 22

---

Actual Collection Time 06:56

---

Specimen Condition \_\_\_\_\_

---

Battery ID RC1029

---

Battery Name TRIGLYCERIDES

---

Lab Test ID RCT19

---

Lab Test Name TRIGLYCERIDES (GPO)

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (1)**


**Generated On: 20 Jul 2016 11:47:42**

---

Test ID

---

Test Status

Done 

---

Reported Text Result

60

---

Reported Numeric Result

60

---

Reference Range low

45

---

Reference Range high

214

---

Range Units

MG/DL

---

Conventional Text Result

---

Conventional Numeric Result

---

Conventional Reference Range Low

---

Conventional Reference Range High

---

Conventional Units

---

SI Text Result

---

SI Numeric Result

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (1)**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (2)**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☐

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6)

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225843

---

Actual Collection Date 2014 01 22

---

Actual Collection Time 06:56

---

Specimen Condition \_\_\_\_\_

---

Battery ID RC1092

---

Battery Name FASTING GLUCOSE

---

Lab Test ID RCT142

---

Lab Test Name FASTING GLUCOSE

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (2)**


**Generated On: 20 Jul 2016 11:47:42**

---

Test ID

---

Test Status

Done 

---

Reported Text Result

89

---

Reported Numeric Result

89

---

Reference Range low

70

---

Reference Range high

100

---

Range Units

MG/DL

---

Conventional Text Result

---

Conventional Numeric Result

---

Conventional Reference Range Low

---

Conventional Reference Range High

---

Conventional Units

---

SI Text Result

---

SI Numeric Result

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (2)**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (3)**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☐

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6)

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225843

---

Actual Collection Date 2014 01 22

---

Actual Collection Time 06:56

---

Specimen Condition \_\_\_\_\_

---

Battery ID RC272

---

Battery Name TOTAL CHOLESTEROL

---

Lab Test ID RCT20

---

Lab Test Name CHOLESTEROL (HIGH  
PERFORMANCE)

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (3)**


**Generated On: 20 Jul 2016 11:47:42**

---

Test ID

---

Test Status

Done 

---

Reported Text Result

162

---

Reported Numeric Result

162

---

Reference Range low

155

---

Reference Range high

265

---

Range Units

MG/DL

---

Conventional Text Result

---

Conventional Numeric Result

---

Conventional Reference Range Low

---

Conventional Reference Range High

---

Conventional Units

---

SI Text Result

---

SI Numeric Result

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (3)**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (4)**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☒

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6) 

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☒

---

Accession ID V225843

---

Actual Collection Date 2014 01 22

---

Actual Collection Time 06:56

---

Specimen Condition \_\_\_\_\_

---

Battery ID RC9255

---

Battery Name CHEMISTRY PANEL

---

Lab Test ID RCT1

---

Lab Test Name TOTAL BILIRUBIN

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (4)**

**Generated On: 20 Jul 2016 11:47:42**

---

Test ID

---

Test Status

Done



---

Reported Text Result

0.3

---

Reported Numeric Result

0.3

---

Reference Range low

0.2

---

Reference Range high

1.2

---

Range Units

MG/DL

---

Conventional Text Result

---

Conventional Numeric Result

---

Conventional Reference Range Low

---

Conventional Reference Range High

---

Conventional Units

---

SI Text Result

---

SI Numeric Result

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (4)**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (5)**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☐

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6)

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225843

---

Actual Collection Date 2014 01 22

---

Actual Collection Time 06:56

---

Specimen Condition \_\_\_\_\_

---

Battery ID RC9255

---

Battery Name CHEMISTRY PANEL

---

Lab Test ID RCT12

---

Lab Test Name TOTAL PROTEIN

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (5)**


**Generated On: 20 Jul 2016 11:47:42**

---

Test ID

---

Test Status

Done 

---

Reported Text Result

6.9

---

Reported Numeric Result

6.9

---

Reference Range low

6.1

---

Reference Range high

8.4

---

Range Units

G/DL

---

Conventional Text Result

---

Conventional Numeric Result

---

Conventional Reference Range Low

---

Conventional Reference Range High

---

Conventional Units

---

SI Text Result

---

SI Numeric Result

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (5)**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (6)**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☐

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6) 

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225843

---

Actual Collection Date 2014 01 22

---

Actual Collection Time 06:56

---

Specimen Condition \_\_\_\_\_

---

Battery ID RC9255

---

Battery Name CHEMISTRY PANEL

---

Lab Test ID RCT13

---

Lab Test Name ALBUMIN

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (6)**


**Generated On: 20 Jul 2016 11:47:42**

---

Test ID

---

Test Status

Done 

---

Reported Text Result

3.8

---

Reported Numeric Result

3.8

---

Reference Range low

3.3

---

Reference Range high

4.9

---

Range Units

G/DL

---

Conventional Text Result

---

Conventional Numeric Result

---

Conventional Reference Range Low

---

Conventional Reference Range High

---

Conventional Units

---

SI Text Result

---

SI Numeric Result

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (6)**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (7)**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☒

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6)

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☒

---

Accession ID V225843

---

Actual Collection Date 2014 01 22

---

Actual Collection Time 06:56

---

Specimen Condition \_\_\_\_\_

---

Battery ID RC9255

---

Battery Name CHEMISTRY PANEL

---

Lab Test ID RCT1407

---

Lab Test Name ALKALINE PHOSPHATASE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (7)**


**Generated On: 20 Jul 2016 11:47:42**

---

Test ID

---

Test Status

Done 

---

Reported Text Result

44

---

Reported Numeric Result

44

---

Reference Range low

31

---

Reference Range high

106

---

Range Units

U/L

---

Conventional Text Result

---

Conventional Numeric Result

---

Conventional Reference Range Low

---

Conventional Reference Range High

---

Conventional Units

---

SI Text Result

---

SI Numeric Result

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (7)**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (8)**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☐

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6) 

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225843

---

Actual Collection Date 2014 01 22

---

Actual Collection Time 06:56

---

Specimen Condition \_\_\_\_\_

---

Battery ID RC9255

---

Battery Name CHEMISTRY PANEL

---

Lab Test ID RCT1408

---

Lab Test Name LDH

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (8)**


**Generated On: 20 Jul 2016 11:47:42**

---

Test ID

---

Test Status

Done 

---

Reported Text Result

127

---

Reported Numeric Result

127

---

Reference Range low

53

---

Reference Range high

234

---

Range Units

U/L

---

Conventional Text Result

---

Conventional Numeric Result

---

Conventional Reference Range Low

---

Conventional Reference Range High

---

Conventional Units

---

SI Text Result

---

SI Numeric Result

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (8)**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (9)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |                                  |
|-------------------|----------------------------------|
| Transmission Type | Cumulative <input type="radio"/> |
|-------------------|----------------------------------|

---

|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

---

|             |   |
|-------------|---|
| Subject Sex | F |
|-------------|---|

---

|                       |   |
|-----------------------|---|
| Subject Date of Birth | (b) (6)  |
|-----------------------|---|

---

|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

---

|            |                                 |
|------------|---------------------------------|
| Visit Type | Scheduled <input type="radio"/> |
|------------|---------------------------------|

---

|              |         |
|--------------|---------|
| Accession ID | V225843 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 01 22 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:56 |
|------------------------|-------|

---

|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

---

|            |        |
|------------|--------|
| Battery ID | RC9255 |
|------------|--------|

---

|              |                 |
|--------------|-----------------|
| Battery Name | CHEMISTRY PANEL |
|--------------|-----------------|

---

|             |       |
|-------------|-------|
| Lab Test ID | RCT15 |
|-------------|-------|

---

|               |              |
|---------------|--------------|
| Lab Test Name | SERUM SODIUM |
|---------------|--------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (9)**


**Generated On: 20 Jul 2016 11:47:42**

---

Test ID

---

Test Status

Done 

---

Reported Text Result

140

---

Reported Numeric Result

140

---

Reference Range low

132

---

Reference Range high

147

---

Range Units

MEQ/L

---

Conventional Text Result

---

Conventional Numeric Result

---

Conventional Reference Range Low

---

Conventional Reference Range High

---

Conventional Units

---

SI Text Result

---

SI Numeric Result

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (9)**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (10)**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☐

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6)

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225843

---

Actual Collection Date 2014 01 22

---

Actual Collection Time 06:56

---

Specimen Condition \_\_\_\_\_

---

Battery ID RC9255

---

Battery Name CHEMISTRY PANEL

---

Lab Test ID RCT16

---

Lab Test Name SERUM POTASSIUM

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (10)**


**Generated On: 20 Jul 2016 11:47:42**

---

Test ID

---

Test Status

Done 

---

Reported Text Result

4.3

---

Reported Numeric Result

4.3

---

Reference Range low

3.4

---

Reference Range high

5.4

---

Range Units

MEQ/L

---

Conventional Text Result

---

Conventional Numeric Result

---

Conventional Reference Range Low

---

Conventional Reference Range High

---

Conventional Units

---

SI Text Result

---

SI Numeric Result

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (10)**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (11)**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☐

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6)

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225843

---

Actual Collection Date 2014 01 22

---

Actual Collection Time 06:56

---

Specimen Condition \_\_\_\_\_

---

Battery ID RC9255

---

Battery Name CHEMISTRY PANEL

---

Lab Test ID RCT29

---

Lab Test Name DIRECT BILIRUBIN

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (11)**


**Generated On: 20 Jul 2016 11:47:42**

---

Test ID

---

Test Status

Done 

---

Reported Text Result

<0.1

---

Reported Numeric Result

---

Reference Range low

0.0

---

Reference Range high

0.4

---

Range Units

MG/DL

---

Conventional Text Result

---

Conventional Numeric Result

---

Conventional Reference Range Low

---

Conventional Reference Range High

---

Conventional Units

---

SI Text Result

---

SI Numeric Result

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (11)**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (12)**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☒

---

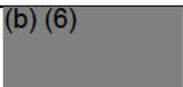
Subject ID or Number 

---

---

Subject Sex F

---

Subject Date of Birth (b) (6) 

---

Visit Name 

---

---

Visit Type Scheduled ☒

---

Accession ID V225843

---

Actual Collection Date 2014 01 22

---

Actual Collection Time 06:56

---

Specimen Condition 

---

---

Battery ID RC9255

---

Battery Name CHEMISTRY PANEL

---

Lab Test ID RCT3

---

Lab Test Name GGT

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (12)**


**Generated On: 20 Jul 2016 11:47:42**

---

Test ID

---

Test Status

Done 

---

Reported Text Result

17

---

Reported Numeric Result

17

---

Reference Range low

4

---

Reference Range high

49

---

Range Units

U/L

---

Conventional Text Result

---

Conventional Numeric Result

---

Conventional Reference Range Low

---

Conventional Reference Range High

---

Conventional Units

---

SI Text Result

---

SI Numeric Result

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (12)**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (13)**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☐

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6) 

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225843

---

Actual Collection Date 2014 01 22

---

Actual Collection Time 06:56

---

Specimen Condition \_\_\_\_\_

---

Battery ID RC9255

---

Battery Name CHEMISTRY PANEL

---

Lab Test ID RCT392

---

Lab Test Name CREATININE (RATE BLANKED)

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (13)**


**Generated On: 20 Jul 2016 11:47:42**

---

Test ID

---

Test Status

Done 

---

Reported Text Result

0.8

---

Reported Numeric Result

0.8

---

Reference Range low

0.4

---

Reference Range high

1.1

---

Range Units

MG/DL

---

Conventional Text Result

---

Conventional Numeric Result

---

Conventional Reference Range Low

---

Conventional Reference Range High

---

Conventional Units

---

SI Text Result

---

SI Numeric Result

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (13)**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (14)**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☐


---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6) 

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225843

---

Actual Collection Date 2014 01 22

---

Actual Collection Time 06:56

---

Specimen Condition \_\_\_\_\_

---

Battery ID RC9255

---

Battery Name CHEMISTRY PANEL

---

Lab Test ID RCT4

---

Lab Test Name ALT (SGPT)

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (14)**


**Generated On: 20 Jul 2016 11:47:42**

---

Test ID

---

Test Status

Done 

---

Reported Text Result

16

---

Reported Numeric Result

16

---

Reference Range low

6

---

Reference Range high

34

---

Range Units

U/L

---

Conventional Text Result

---

Conventional Numeric Result

---

Conventional Reference Range Low

---

Conventional Reference Range High

---

Conventional Units

---

SI Text Result

---

SI Numeric Result

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (14)**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (15)**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☐

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6) 

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225843

---

Actual Collection Date 2014 01 22

---

Actual Collection Time 06:56

---

Specimen Condition \_\_\_\_\_

---

Battery ID RC9255

---

Battery Name CHEMISTRY PANEL

---

Lab Test ID RCT5

---

Lab Test Name AST (SGOT)

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (15)**


**Generated On: 20 Jul 2016 11:47:42**

---

Test ID

---

Test Status

Done 

---

Reported Text Result

16

---

Reported Numeric Result

16

---

Reference Range low

9

---

Reference Range high

34

---

Range Units

U/L

---

Conventional Text Result

---

Conventional Numeric Result

---

Conventional Reference Range Low

---

Conventional Reference Range High

---

Conventional Units

---

SI Text Result

---

SI Numeric Result

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (15)**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (16)**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☒


---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6) 

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☒

---

Accession ID V225843

---

Actual Collection Date 2014 01 22

---

Actual Collection Time 06:56

---

Specimen Condition \_\_\_\_\_

---

Battery ID RC9255

---

Battery Name CHEMISTRY PANEL

---

Lab Test ID RCT6

---

Lab Test Name UREA NITROGEN

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (16)**


**Generated On: 20 Jul 2016 11:47:42**

---

Test ID

---

Test Status

Done 

---

Reported Text Result

14

---

Reported Numeric Result

14

---

Reference Range low

4

---

Reference Range high

24

---

Range Units

MG/DL

---

Conventional Text Result

---

Conventional Numeric Result

---

Conventional Reference Range Low

---

Conventional Reference Range High

---

Conventional Units

---

SI Text Result

---

SI Numeric Result

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (16)**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (17)**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☐

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6) 

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225843

---

Actual Collection Date 2014 01 22

---

Actual Collection Time 06:56

---

Specimen Condition \_\_\_\_\_

---

Battery ID HM1604

---

Battery Name HEMATOLOGY  
&DIFFERENTIAL PANEL

---

Lab Test ID HMT10

---

Lab Test Name MONOCYTES

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (17)**


**Generated On: 20 Jul 2016 11:47:42**

---

Test ID

---

Test Status

Done 

---

Reported Text Result

0.39

---

Reported Numeric Result

0.39

---

Reference Range low

0.12

---

Reference Range high

0.92

---

Range Units

X10<sup>3</sup>/UL

---

Conventional Text Result

---

Conventional Numeric Result

---

Conventional Reference Range Low

---

Conventional Reference Range High

---

Conventional Units

---

SI Text Result

---

SI Numeric Result

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (17)**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (18)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |                                  |
|-------------------|----------------------------------|
| Transmission Type | Cumulative <input type="radio"/> |
|-------------------|----------------------------------|

---

|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

---

|             |   |
|-------------|---|
| Subject Sex | F |
|-------------|---|

---

|                       |   |
|-----------------------|---|
| Subject Date of Birth | (b) (6)  |
|-----------------------|---|

---

|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

---

|            |                                 |
|------------|---------------------------------|
| Visit Type | Scheduled <input type="radio"/> |
|------------|---------------------------------|

---

|              |         |
|--------------|---------|
| Accession ID | V225843 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 01 22 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:56 |
|------------------------|-------|

---

|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

---

|            |        |
|------------|--------|
| Battery ID | HM1604 |
|------------|--------|

---

|              |                                   |
|--------------|-----------------------------------|
| Battery Name | HEMATOLOGY<br>&DIFFERENTIAL PANEL |
|--------------|-----------------------------------|

---

|             |        |
|-------------|--------|
| Lab Test ID | HMT100 |
|-------------|--------|

---

|               |     |
|---------------|-----|
| Lab Test Name | MCH |
|---------------|-----|

---

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (18)**


**Generated On: 20 Jul 2016 11:47:42**

---

Test ID

---

Test Status

Done 

---

Reported Text Result

29

---

Reported Numeric Result

29

---

Reference Range low

26

---

Reference Range high

34

---

Range Units

PG

---

Conventional Text Result

---

Conventional Numeric Result

---

Conventional Reference Range Low

---

Conventional Reference Range High

---

Conventional Units

---

SI Text Result

---

SI Numeric Result

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (18)**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (19)**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☐

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6) 

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225843

---

Actual Collection Date 2014 01 22

---

Actual Collection Time 06:56

---

Specimen Condition \_\_\_\_\_

---

Battery ID HM1604

---

Battery Name HEMATOLOGY  
&DIFFERENTIAL PANEL

---

Lab Test ID HMT102

---

Lab Test Name MCHC

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (19)**


**Generated On: 20 Jul 2016 11:47:42**

---

Test ID

---

Test Status

Done 

---

Reported Text Result

32

---

Reported Numeric Result

32

---

Reference Range low

31

---

Reference Range high

38

---

Range Units

G/DL

---

Conventional Text Result

---

Conventional Numeric Result

---

Conventional Reference Range Low

---

Conventional Reference Range High

---

Conventional Units

---

SI Text Result

---

SI Numeric Result

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (19)**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (20)**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☐

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6) 

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225843

---

Actual Collection Date 2014 01 22

---

Actual Collection Time 06:56

---

Specimen Condition \_\_\_\_\_

---

Battery ID HM1604

---

Battery Name HEMATOLOGY  
&DIFFERENTIAL PANEL

---

Lab Test ID HMT11

---

Lab Test Name EOSINOPHILS

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (20)**

**Generated On: 20 Jul 2016 11:47:42**

---

Test ID

---

Test Status

Done



---

Reported Text Result

0.18

---

Reported Numeric Result

0.18

---

Reference Range low

0.00

---

Reference Range high

0.57

---

Range Units

X10<sup>3</sup>/UL

---

Conventional Text Result

---

Conventional Numeric Result

---

Conventional Reference Range Low

---

Conventional Reference Range High

---

Conventional Units

---

SI Text Result

---

SI Numeric Result

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (20)**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (21)**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☐

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6) 

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225843

---

Actual Collection Date 2014 01 22

---

Actual Collection Time 06:56

---

Specimen Condition \_\_\_\_\_

---

Battery ID HM1604

---

Battery Name HEMATOLOGY  
&DIFFERENTIAL PANEL

---

Lab Test ID HMT12

---

Lab Test Name BASOPHILS

---

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (21)**


**Generated On: 20 Jul 2016 11:47:42**

---

Test ID

---

Test Status

Done 

---

Reported Text Result

0.11

---

Reported Numeric Result

0.11

---

Reference Range low

0.00

---

Reference Range high

0.20

---

Range Units

X10<sup>3</sup>/UL

---

Conventional Text Result

---

Conventional Numeric Result

---

Conventional Reference Range Low

---

Conventional Reference Range High

---

Conventional Units

---

SI Text Result

---

SI Numeric Result

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (21)**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (22)**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☐

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6) 

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225843

---

Actual Collection Date 2014 01 22

---

Actual Collection Time 06:56

---

Specimen Condition \_\_\_\_\_

---

Battery ID HM1604

---

Battery Name HEMATOLOGY  
&DIFFERENTIAL PANEL

---

Lab Test ID HMT13

---

Lab Test Name PLATELETS

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (22)**


**Generated On: 20 Jul 2016 11:47:42**

---

Test ID

---

Test Status

Done 

---

Reported Text Result

264

---

Reported Numeric Result

264

---

Reference Range low

140

---

Reference Range high

400

---

Range Units

X10<sup>3</sup>/UL

---

Conventional Text Result

---

Conventional Numeric Result

---

Conventional Reference Range Low

---

Conventional Reference Range High

---

Conventional Units

---

SI Text Result

---

SI Numeric Result

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (22)**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (23)**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☐

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6)

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225843

---

Actual Collection Date 2014 01 22

---

Actual Collection Time 06:56

---

Specimen Condition \_\_\_\_\_

---

Battery ID HM1604

---

Battery Name HEMATOLOGY  
&DIFFERENTIAL PANEL

---

Lab Test ID HMT15

---

Lab Test Name NEUTROPHILS (%)

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (23)**


**Generated On: 20 Jul 2016 11:47:42**

---

Test ID

---

Test Status

Done 

---

Reported Text Result 50.9

---

Reported Numeric Result 50.9

---

Reference Range low 40.5

---

Reference Range high 75.0

---

Range Units %

---

Conventional Text Result

---

Conventional Numeric Result

---

Conventional Reference Range Low

---

Conventional Reference Range High

---

Conventional Units

---

SI Text Result

---

SI Numeric Result

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (23)**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (24)**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☐

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6) 

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225843

---

Actual Collection Date 2014 01 22

---

Actual Collection Time 06:56

---

Specimen Condition \_\_\_\_\_

---

Battery ID HM1604

---

Battery Name HEMATOLOGY  
&DIFFERENTIAL PANEL

---

Lab Test ID HMT16

---

Lab Test Name LYMPHOCYTES (%)

---

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (24)**


**Generated On: 20 Jul 2016 11:47:42**

---

Test ID

---

Test Status

Done 

---

Reported Text Result

36.7

---

Reported Numeric Result

36.7

---

Reference Range low

15.4

---

Reference Range high

48.5

---

Range Units

%

---

Conventional Text Result

---

Conventional Numeric Result

---

Conventional Reference Range Low

---

Conventional Reference Range High

---

Conventional Units

---

SI Text Result

---

SI Numeric Result

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (24)**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (25)**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☐

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6)

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225843

---

Actual Collection Date 2014 01 22

---

Actual Collection Time 06:56

---

Specimen Condition \_\_\_\_\_

---

Battery ID HM1604

---

Battery Name HEMATOLOGY  
&DIFFERENTIAL PANEL

---

Lab Test ID HMT17

---

Lab Test Name MONOCYTES (%)

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (25)**

**Generated On: 20 Jul 2016 11:47:42**

---

Test ID

---

Test Status

Done



---

Reported Text Result

7.1

---

Reported Numeric Result

7.1

---

Reference Range low

2.6

---

Reference Range high

10.1

---

Range Units

%

---

Conventional Text Result

---

Conventional Numeric Result

---

Conventional Reference Range Low

---

Conventional Reference Range High

---

Conventional Units

---

SI Text Result

---

SI Numeric Result

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (25)**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (26)**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☐

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6)

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225843

---

Actual Collection Date 2014 01 22

---

Actual Collection Time 06:56

---

Specimen Condition \_\_\_\_\_

---

Battery ID HM1604

---

Battery Name HEMATOLOGY  
&DIFFERENTIAL PANEL

---

Lab Test ID HMT18

---

Lab Test Name EOSINOPHILS (%)

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (26)**


**Generated On: 20 Jul 2016 11:47:42**

---

Test ID

---

Test Status

Done 

---

Reported Text Result

3.2

---

Reported Numeric Result

3.2

---

Reference Range low

0.0

---

Reference Range high

6.8

---

Range Units

%

---

Conventional Text Result

---

Conventional Numeric Result

---

Conventional Reference Range Low

---

Conventional Reference Range High

---

Conventional Units

---

SI Text Result

---

SI Numeric Result

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (26)**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (27)**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☐

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6) 

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225843

---

Actual Collection Date 2014 01 22

---

Actual Collection Time 06:56

---

Specimen Condition \_\_\_\_\_

---

Battery ID HM1604

---

Battery Name HEMATOLOGY  
&DIFFERENTIAL PANEL

---

Lab Test ID HMT19

---

Lab Test Name BASOPHILS (%)

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (27)**


**Generated On: 20 Jul 2016 11:47:42**

---

Test ID

---

Test Status

Done 

---

Reported Text Result

2.0

---

Reported Numeric Result

2.0

---

Reference Range low

0.0

---

Reference Range high

2.0

---

Range Units

%

---

Conventional Text Result

---

Conventional Numeric Result

---

Conventional Reference Range Low

---

Conventional Reference Range High

---

Conventional Units

---

SI Text Result

---

SI Numeric Result

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (27)**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (28)**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☐

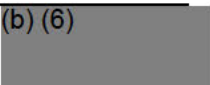
---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6) 

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225843

---

Actual Collection Date 2014 01 22

---

Actual Collection Time 06:56

---

Specimen Condition \_\_\_\_\_

---

Battery ID HM1604

---

Battery Name HEMATOLOGY  
&DIFFERENTIAL PANEL

---

Lab Test ID HMT2

---

Lab Test Name HEMATOCRIT

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (28)**


**Generated On: 20 Jul 2016 11:47:42**

---

Test ID

---

Test Status

Done 

---

Reported Text Result

36

---

Reported Numeric Result

36

---

Reference Range low

34

---

Reference Range high

48

---

Range Units

%

---

Conventional Text Result

---

Conventional Numeric Result

---

Conventional Reference Range Low

---

Conventional Reference Range High

---

Conventional Units

---

SI Text Result

---

SI Numeric Result

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (28)**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (29)**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☐

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6)

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225843

---

Actual Collection Date 2014 01 22

---

Actual Collection Time 06:56

---

Specimen Condition \_\_\_\_\_

---

Battery ID HM1604

---

Battery Name HEMATOLOGY  
&DIFFERENTIAL PANEL

---

Lab Test ID HMT3

---

Lab Test Name RBC

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (29)**


**Generated On: 20 Jul 2016 11:47:42**

---

Test ID

---

Test Status

Done 

---

Reported Text Result

4.0

---

Reported Numeric Result

4.0

---

Reference Range low

4.1

---

Reference Range high

5.6

---

Range Units

X10<sup>6</sup>/UL

---

Conventional Text Result

---

Conventional Numeric Result

---

Conventional Reference Range Low

---

Conventional Reference Range High

---

Conventional Units

---

SI Text Result

---

SI Numeric Result

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (29)**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

Low



---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (30)**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☐


---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6) 

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225843

---

Actual Collection Date 2014 01 22

---

Actual Collection Time 06:56

---

Specimen Condition \_\_\_\_\_

---

Battery ID HM1604

---

Battery Name HEMATOLOGY  
&DIFFERENTIAL PANEL

---

Lab Test ID HMT4

---

Lab Test Name MCV

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (30)**


**Generated On: 20 Jul 2016 11:47:42**

---

Test ID

---

Test Status

Done 

---

Reported Text Result

91

---

Reported Numeric Result

91

---

Reference Range low

79

---

Reference Range high

98

---

Range Units

FL

---

Conventional Text Result

---

Conventional Numeric Result

---

Conventional Reference Range Low

---

Conventional Reference Range High

---

Conventional Units

---

SI Text Result

---

SI Numeric Result

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (30)**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (31)**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☐

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6)

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225843

---

Actual Collection Date 2014 01 22

---

Actual Collection Time 06:56

---

Specimen Condition \_\_\_\_\_

---

Battery ID HM1604

---

Battery Name HEMATOLOGY  
&DIFFERENTIAL PANEL

---

Lab Test ID HMT40

---

Lab Test Name HEMOGLOBIN

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (31)**

**Generated On: 20 Jul 2016 11:47:42**

---

Test ID

---

Test Status

Done



---

Reported Text Result

11.5

---

Reported Numeric Result

11.5

---

Reference Range low

11.6

---

Reference Range high

16.4

---

Range Units

G/DL

---

Conventional Text Result

---

Conventional Numeric Result

---

Conventional Reference Range Low

---

Conventional Reference Range High

---

Conventional Units

---

SI Text Result

---

SI Numeric Result

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (31)**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

Low



---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (32)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

---

|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

---

|             |   |
|-------------|---|
| Subject Sex | F |
|-------------|---|

---

|                       |   |
|-----------------------|---|
| Subject Date of Birth | (b) (6)  |
|-----------------------|---|

---

|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | V225843 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 01 22 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:56 |
|------------------------|-------|

---

|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

---

|            |        |
|------------|--------|
| Battery ID | HM1604 |
|------------|--------|

---

|              |                                   |
|--------------|-----------------------------------|
| Battery Name | HEMATOLOGY<br>&DIFFERENTIAL PANEL |
|--------------|-----------------------------------|

---

|             |      |
|-------------|------|
| Lab Test ID | HMT7 |
|-------------|------|

---

|               |     |
|---------------|-----|
| Lab Test Name | WBC |
|---------------|-----|

---

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (32)**


**Generated On: 20 Jul 2016 11:47:42**

---

Test ID

---

Test Status

Done 

---

Reported Text Result

5.49

---

Reported Numeric Result

5.49

---

Reference Range low

3.80

---

Reference Range high

10.70

---

Range Units

X10<sup>3</sup>/UL

---

Conventional Text Result

---

Conventional Numeric Result

---

Conventional Reference Range Low

---

Conventional Reference Range High

---

Conventional Units

---

SI Text Result

---

SI Numeric Result

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (32)**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (33)**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☐

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6) 

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225843

---

Actual Collection Date 2014 01 22

---

Actual Collection Time 06:56

---

Specimen Condition \_\_\_\_\_

---

Battery ID HM1604

---

Battery Name HEMATOLOGY  
&DIFFERENTIAL PANEL

---

Lab Test ID HMT71

---

Lab Test Name RBC MORPHOLOGY 1

---

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (33)**

**Generated On: 20 Jul 2016 11:47:42**

---

Test ID

---

Test Status

Done



---

Reported Text Result

NORMOCYTIC

---

Reported Numeric Result

---

Reference Range low

---

Reference Range high

---

Range Units

---

Conventional Text Result

---

Conventional Numeric Result

---

Conventional Reference Range Low

---

Conventional Reference Range High

---

Conventional Units

---

SI Text Result

---

SI Numeric Result

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (33)**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (34)**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☐

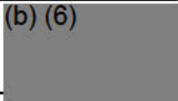
---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6) 

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225843

---

Actual Collection Date 2014 01 22

---

Actual Collection Time 06:56

---

Specimen Condition \_\_\_\_\_

---

Battery ID HM1604

---

Battery Name HEMATOLOGY  
&DIFFERENTIAL PANEL

---

Lab Test ID HMT8

---

Lab Test Name NEUTROPHILS

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (34)**


**Generated On: 20 Jul 2016 11:47:42**

---

Test ID

---

Test Status

Done 

---

Reported Text Result

2.80

---

Reported Numeric Result

2.80

---

Reference Range low

1.96

---

Reference Range high

7.23

---

Range Units

X10<sup>3</sup>/UL

---

Conventional Text Result

---

Conventional Numeric Result

---

Conventional Reference Range Low

---

Conventional Reference Range High

---

Conventional Units

---

SI Text Result

---

SI Numeric Result

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (34)**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (35)**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☐

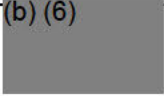
---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6) 

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225843

---

Actual Collection Date 2014 01 22

---

Actual Collection Time 06:56

---

Specimen Condition \_\_\_\_\_

---

Battery ID HM1604

---

Battery Name HEMATOLOGY  
&DIFFERENTIAL PANEL

---

Lab Test ID HMT9

---

Lab Test Name LYMPHOCYTES

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (35)**


**Generated On: 20 Jul 2016 11:47:42**

---

Test ID

---

Test Status

Done 

---

Reported Text Result

2.02

---

Reported Numeric Result

2.02

---

Reference Range low

0.91

---

Reference Range high

4.28

---

Range Units

X10<sup>3</sup>/UL

---

Conventional Text Result

---

Conventional Numeric Result

---

Conventional Reference Range Low

---

Conventional Reference Range High

---

Conventional Units

---

SI Text Result

---

SI Numeric Result

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (35)**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (36)**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☐

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6) 

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225843

---

Actual Collection Date 2014 01 22

---

Actual Collection Time 06:56

---

Specimen Condition \_\_\_\_\_

---

Battery ID UA1538

---

Battery Name URINE MACRO PANEL

---

Lab Test ID UAT10

---

Lab Test Name UR NITRITE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (36)**


**Generated On: 20 Jul 2016 11:47:42**

---

Test ID

---

Test Status

Done 

---

Reported Text Result

NEGATIVE

---

Reported Numeric Result

---

Reference Range low

---

Reference Range high

---

Range Units

---

Conventional Text Result

---

Conventional Numeric Result

---

Conventional Reference Range Low

---

Conventional Reference Range High

---

Conventional Units

---

SI Text Result

---

SI Numeric Result

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (36)**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (37)**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☐

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6) 

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225843

---

Actual Collection Date 2014 01 22

---

Actual Collection Time 06:56

---

Specimen Condition \_\_\_\_\_

---

Battery ID UA1538

---

Battery Name URINE MACRO PANEL

---

Lab Test ID UAT2

---

Lab Test Name UR SPECIFIC GRAVITY

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (37)**


**Generated On: 20 Jul 2016 11:47:42**

---

Test ID

---

Test Status

Done 

---

Reported Text Result

1.021

---

Reported Numeric Result

1.021

---

Reference Range low

1.003

---

Reference Range high

1.035

---

Range Units

---

Conventional Text Result

---

Conventional Numeric Result

---

Conventional Reference Range Low

---

Conventional Reference Range High

---

Conventional Units

---

SI Text Result

---

SI Numeric Result

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (37)**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (38)**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☐

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6) 

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225843

---

Actual Collection Date 2014 01 22

---

Actual Collection Time 06:56

---

Specimen Condition \_\_\_\_\_

---

Battery ID UA1538

---

Battery Name URINE MACRO PANEL

---

Lab Test ID UAT3

---

Lab Test Name UR PH

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (38)**


**Generated On: 20 Jul 2016 11:47:42**

---

Test ID

---

Test Status

Done 

---

Reported Text Result

6.5

---

Reported Numeric Result

6.5

---

Reference Range low

5.0

---

Reference Range high

8.0

---

Range Units

---

Conventional Text Result

---

Conventional Numeric Result

---

Conventional Reference Range Low

---

Conventional Reference Range High

---

Conventional Units

---

SI Text Result

---

SI Numeric Result

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (38)**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (39)**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☒

---

Subject ID or Number 

---

---

Subject Sex F

---

Subject Date of Birth (b) (6)

---

Visit Name 

---

---

Visit Type Scheduled ☒

---

Accession ID V225843

---

Actual Collection Date 2014 01 22

---

Actual Collection Time 06:56

---

Specimen Condition 

---

---

Battery ID UA1538

---

Battery Name URINE MACRO PANEL

---

Lab Test ID UAT43

---

Lab Test Name UR BLOOD

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (39)**


**Generated On: 20 Jul 2016 11:47:42**

---

Test ID

---

Test Status

Done 

---

Reported Text Result

NEGATIVE

---

Reported Numeric Result

---

Reference Range low

---

Reference Range high

---

Range Units

---

Conventional Text Result

---

Conventional Numeric Result

---

Conventional Reference Range Low

---

Conventional Reference Range High

---

Conventional Units

---

SI Text Result

---

SI Numeric Result

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (39)**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (40)**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☒

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6) 

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☒

---

Accession ID V225843

---

Actual Collection Date 2014 01 22

---

Actual Collection Time 06:56

---

Specimen Condition \_\_\_\_\_

---

Battery ID UA1538

---

Battery Name URINE MACRO PANEL

---

Lab Test ID UAT49

---

Lab Test Name UR PROTEIN

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (40)**

**Generated On: 20 Jul 2016 11:47:42**

---

Test ID

---

Test Status

Done



---

Reported Text Result

TRACE

---

Reported Numeric Result

---

Reference Range low

---

Reference Range high

---

Range Units

---

Conventional Text Result

---

Conventional Numeric Result

---

Conventional Reference Range Low

---

Conventional Reference Range High

---

Conventional Units

---

SI Text Result

---

SI Numeric Result

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (40)**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

High ☒

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (41)**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☐

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6) 

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225843

---

Actual Collection Date 2014 01 22

---

Actual Collection Time 06:56

---

Specimen Condition \_\_\_\_\_

---

Battery ID UA1538

---

Battery Name URINE MACRO PANEL

---

Lab Test ID UAT5

---

Lab Test Name UR GLUCOSE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (41)**

**Generated On: 20 Jul 2016 11:47:42**

---

Test ID

---

Test Status

Done



---

Reported Text Result

NORMAL

---

Reported Numeric Result

---

Reference Range low

---

Reference Range high

---

Range Units

---

Conventional Text Result

---

Conventional Numeric Result

---

Conventional Reference Range Low

---

Conventional Reference Range High

---

Conventional Units

---

SI Text Result

---

SI Numeric Result

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (41)**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (42)**

**Generated On: 20 Jul 2016 11:47:42**

---

Transmission Type Cumulative ☐


---

Subject ID or Number \_\_\_\_\_

---

Subject Sex F

---

Subject Date of Birth (b) (6) 

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID V225843

---

Actual Collection Date 2014 01 22

---

Actual Collection Time 06:56

---

Specimen Condition \_\_\_\_\_

---

Battery ID UA1538

---

Battery Name URINE MACRO PANEL

---

Lab Test ID UAT7

---

Lab Test Name UR BILIRUBIN

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (42)**


**Generated On: 20 Jul 2016 11:47:42**

---

Test ID

---

Test Status

Done 

---

Reported Text Result

NEGATIVE

---

Reported Numeric Result

---

Reference Range low

---

Reference Range high

---

Range Units

---

Conventional Text Result

---

Conventional Numeric Result

---

Conventional Reference Range Low

---

Conventional Reference Range High

---

Conventional Units

---

SI Text Result

---

SI Numeric Result

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (42)**

**Generated On: 20 Jul 2016 11:47:42**

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-mCC**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:40**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-mCC (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:40**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 15 JAN 2014 |
|------------------------------------|-------------|

---

|       |   |
|-------|---|
| Visit | Day -1 <input checked="" type="radio"/> |
|-------|---|

---

|                     |                                      |
|---------------------|--------------------------------------|
| Type of Product Use | mCC <input checked="" type="radio"/> |
|---------------------|--------------------------------------|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 06:57 |
|----------------------|-------|

---

|                     |       |
|---------------------|-------|
| Time of butt return | 07:06 |
|---------------------|-------|

---

|                |       |
|----------------|-------|
| CC with SODIM? | False |
|----------------|-------|

---

|                    |       |
|--------------------|-------|
| CC not compatible? | False |
|--------------------|-------|

---

|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

---

|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-mCC (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:40**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-mCC (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:40**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 15 JAN 2014 |
|------------------------------------|-------------|

---

|       |   |
|-------|---|
| Visit | Day -1 <input checked="" type="radio"/> |
|-------|---|

---

|                     |                                      |
|---------------------|--------------------------------------|
| Type of Product Use | mCC <input checked="" type="radio"/> |
|---------------------|--------------------------------------|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 08:00 |
|----------------------|-------|

---

|                     |       |
|---------------------|-------|
| Time of butt return | 08:10 |
|---------------------|-------|

---

|                |       |
|----------------|-------|
| CC with SODIM? | False |
|----------------|-------|

---

|                    |       |
|--------------------|-------|
| CC not compatible? | False |
|--------------------|-------|

---

|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

---

|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-mCC (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:40**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-mCC (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:40**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 15 JAN 2014 |
|------------------------------------|-------------|

---

|       |   |
|-------|---|
| Visit | Day -1 <input checked="" type="radio"/> |
|-------|---|

---

|                     |                                      |
|---------------------|--------------------------------------|
| Type of Product Use | mCC <input checked="" type="radio"/> |
|---------------------|--------------------------------------|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 08:42 |
|----------------------|-------|

---

|                     |       |
|---------------------|-------|
| Time of butt return | 08:52 |
|---------------------|-------|

---

|                |       |
|----------------|-------|
| CC with SODIM? | False |
|----------------|-------|

---

|                    |       |
|--------------------|-------|
| CC not compatible? | False |
|--------------------|-------|

---

|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

---

|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-mCC (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:40**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-mCC (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:40**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 15 JAN 2014 |
|------------------------------------|-------------|

---

|       |   |
|-------|---|
| Visit | Day -1 <input checked="" type="radio"/> |
|-------|---|

---

|                     |                                      |
|---------------------|--------------------------------------|
| Type of Product Use | mCC <input checked="" type="radio"/> |
|---------------------|--------------------------------------|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 10:28 |
|----------------------|-------|

---

|                     |       |
|---------------------|-------|
| Time of butt return | 10:38 |
|---------------------|-------|

---

|                |       |
|----------------|-------|
| CC with SODIM? | False |
|----------------|-------|

---

|                    |       |
|--------------------|-------|
| CC not compatible? | False |
|--------------------|-------|

---

|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

---

|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-mCC (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:40**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-mCC (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:40**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 15 JAN 2014 |
|------------------------------------|-------------|

---

|       |   |
|-------|---|
| Visit | Day -1 <input checked="" type="radio"/> |
|-------|---|

---

|                     |                                      |
|---------------------|--------------------------------------|
| Type of Product Use | mCC <input checked="" type="radio"/> |
|---------------------|--------------------------------------|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 13:13 |
|----------------------|-------|

---

|                     |       |
|---------------------|-------|
| Time of butt return | 13:23 |
|---------------------|-------|

---

|                |       |
|----------------|-------|
| CC with SODIM? | False |
|----------------|-------|

---

|                    |       |
|--------------------|-------|
| CC not compatible? | False |
|--------------------|-------|

---

|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

---

|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-mCC (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:40**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-mCC (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:40**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 15 JAN 2014 |
|------------------------------------|-------------|

---

|       |   |
|-------|---|
| Visit | Day -1 <input checked="" type="radio"/> |
|-------|---|

---

|                     |                                      |
|---------------------|--------------------------------------|
| Type of Product Use | mCC <input checked="" type="radio"/> |
|---------------------|--------------------------------------|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 14:23 |
|----------------------|-------|

---

|                     |       |
|---------------------|-------|
| Time of butt return | 14:33 |
|---------------------|-------|

---

|                |       |
|----------------|-------|
| CC with SODIM? | False |
|----------------|-------|

---

|                    |       |
|--------------------|-------|
| CC not compatible? | False |
|--------------------|-------|

---

|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

---

|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-mCC (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:40**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-mCC (7)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:40**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 15 JAN 2014 |
|------------------------------------|-------------|

---

|       |   |
|-------|---|
| Visit | Day -1 <input checked="" type="radio"/> |
|-------|---|

---

|                     |                                      |
|---------------------|--------------------------------------|
| Type of Product Use | mCC <input checked="" type="radio"/> |
|---------------------|--------------------------------------|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 16:40 |
|----------------------|-------|

---

|                     |       |
|---------------------|-------|
| Time of butt return | 16:51 |
|---------------------|-------|

---

|                |       |
|----------------|-------|
| CC with SODIM? | False |
|----------------|-------|

---

|                    |       |
|--------------------|-------|
| CC not compatible? | False |
|--------------------|-------|

---

|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

---

|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-mCC (7)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:40**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-mCC (8)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:40**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 15 JAN 2014 |
|------------------------------------|-------------|

---

|       |   |
|-------|---|
| Visit | Day -1 <input checked="" type="radio"/> |
|-------|---|

---

|                     |                                      |
|---------------------|--------------------------------------|
| Type of Product Use | mCC <input checked="" type="radio"/> |
|---------------------|--------------------------------------|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 18:22 |
|----------------------|-------|

---

|                     |       |
|---------------------|-------|
| Time of butt return | 18:30 |
|---------------------|-------|

---

|                |       |
|----------------|-------|
| CC with SODIM? | False |
|----------------|-------|

---

|                    |       |
|--------------------|-------|
| CC not compatible? | False |
|--------------------|-------|

---

|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

---

|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-mCC (8)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:40**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-mCC (9)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:40**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 15 JAN 2014 |
|------------------------------------|-------------|

---

|       |   |
|-------|---|
| Visit | Day -1 <input checked="" type="radio"/> |
|-------|---|

---

|                     |                                      |
|---------------------|--------------------------------------|
| Type of Product Use | mCC <input checked="" type="radio"/> |
|---------------------|--------------------------------------|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 20:55 |
|----------------------|-------|

---

|                     |       |
|---------------------|-------|
| Time of butt return | 21:04 |
|---------------------|-------|

---

|                |       |
|----------------|-------|
| CC with SODIM? | False |
|----------------|-------|

---

|                    |       |
|--------------------|-------|
| CC not compatible? | False |
|--------------------|-------|

---

|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

---

|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-mCC (9)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:40**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-mCC (10)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:40**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 15 JAN 2014 |
|------------------------------------|-------------|

---

|       |   |
|-------|---|
| Visit | Day -1 <input checked="" type="radio"/> |
|-------|---|

---

|                     |                                      |
|---------------------|--------------------------------------|
| Type of Product Use | mCC <input checked="" type="radio"/> |
|---------------------|--------------------------------------|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 22:02 |
|----------------------|-------|

---

|                     |       |
|---------------------|-------|
| Time of butt return | 22:16 |
|---------------------|-------|

---

|                |       |
|----------------|-------|
| CC with SODIM? | False |
|----------------|-------|

---

|                    |       |
|--------------------|-------|
| CC not compatible? | False |
|--------------------|-------|

---

|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

---

|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-mCC (10)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:40**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-mCC (11)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:40**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 16 JAN 2014 |
|------------------------------------|-------------|

---

|       |  |
|-------|--|
| Visit | Day 0 <input checked="" type="radio"/> |
|-------|--|

---

|                     |                                      |
|---------------------|--------------------------------------|
| Type of Product Use | mCC <input checked="" type="radio"/> |
|---------------------|--------------------------------------|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 09:17 |
|----------------------|-------|

---

|                     |       |
|---------------------|-------|
| Time of butt return | 09:28 |
|---------------------|-------|

---

|                |      |
|----------------|------|
| CC with SODIM? | True |
|----------------|------|

---

|                    |       |
|--------------------|-------|
| CC not compatible? | False |
|--------------------|-------|

---

|                     |     |
|---------------------|-----|
| SODIM device number | 164 |
|---------------------|-----|

---

|                            |     |
|----------------------------|-----|
| SODIM sample holder number | 207 |
|----------------------------|-----|

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10207001 |
|-------------------|----------------------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-mCC (11)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:40**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-mCC (12)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:40**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 16 JAN 2014 |
|------------------------------------|-------------|

---

|       |  |
|-------|--|
| Visit | Day 0 <input checked="" type="radio"/> |
|-------|--|

---

|                     |                                      |
|---------------------|--------------------------------------|
| Type of Product Use | mCC <input checked="" type="radio"/> |
|---------------------|--------------------------------------|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 10:57 |
|----------------------|-------|

---

|                     |       |
|---------------------|-------|
| Time of butt return | 11:10 |
|---------------------|-------|

---

|                |      |
|----------------|------|
| CC with SODIM? | True |
|----------------|------|

---

|                    |       |
|--------------------|-------|
| CC not compatible? | False |
|--------------------|-------|

---

|                     |     |
|---------------------|-----|
| SODIM device number | 164 |
|---------------------|-----|

---

|                            |     |
|----------------------------|-----|
| SODIM sample holder number | 207 |
|----------------------------|-----|

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10207002 |
|-------------------|----------------------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-mCC (12)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:40**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-mCC (13)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:40**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 16 JAN 2014 |
|------------------------------------|-------------|

---

|       |  |
|-------|--|
| Visit | Day 0 <input checked="" type="radio"/> |
|-------|--|

---

|                     |                                      |
|---------------------|--------------------------------------|
| Type of Product Use | mCC <input checked="" type="radio"/> |
|---------------------|--------------------------------------|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 12:17 |
|----------------------|-------|

---

|                     |       |
|---------------------|-------|
| Time of butt return | 12:28 |
|---------------------|-------|

---

|                |      |
|----------------|------|
| CC with SODIM? | True |
|----------------|------|

---

|                    |       |
|--------------------|-------|
| CC not compatible? | False |
|--------------------|-------|

---

|                     |     |
|---------------------|-----|
| SODIM device number | 164 |
|---------------------|-----|

---

|                            |     |
|----------------------------|-----|
| SODIM sample holder number | 207 |
|----------------------------|-----|

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10207003 |
|-------------------|----------------------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-mCC (13)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:40**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-mCC (14)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:40**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 16 JAN 2014 |
|------------------------------------|-------------|

---

|       |  |
|-------|--|
| Visit | Day 0 <input checked="" type="radio"/> |
|-------|--|

---

|                     |                                      |
|---------------------|--------------------------------------|
| Type of Product Use | mCC <input checked="" type="radio"/> |
|---------------------|--------------------------------------|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 13:19 |
|----------------------|-------|

---

|                     |       |
|---------------------|-------|
| Time of butt return | 13:31 |
|---------------------|-------|

---

|                |      |
|----------------|------|
| CC with SODIM? | True |
|----------------|------|

---

|                    |       |
|--------------------|-------|
| CC not compatible? | False |
|--------------------|-------|

---

|                     |     |
|---------------------|-----|
| SODIM device number | 164 |
|---------------------|-----|

---

|                            |     |
|----------------------------|-----|
| SODIM sample holder number | 207 |
|----------------------------|-----|

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10207004 |
|-------------------|----------------------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-mCC (14)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:40**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-mCC (15)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:40**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 16 JAN 2014 |
|------------------------------------|-------------|

---

|       |  |
|-------|--|
| Visit | Day 0 <input checked="" type="radio"/> |
|-------|--|

---

|                     |                                      |
|---------------------|--------------------------------------|
| Type of Product Use | mCC <input checked="" type="radio"/> |
|---------------------|--------------------------------------|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 14:19 |
|----------------------|-------|

---

|                     |       |
|---------------------|-------|
| Time of butt return | 14:28 |
|---------------------|-------|

---

|                |      |
|----------------|------|
| CC with SODIM? | True |
|----------------|------|

---

|                    |       |
|--------------------|-------|
| CC not compatible? | False |
|--------------------|-------|

---

|                     |     |
|---------------------|-----|
| SODIM device number | 164 |
|---------------------|-----|

---

|                            |     |
|----------------------------|-----|
| SODIM sample holder number | 207 |
|----------------------------|-----|

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10207005 |
|-------------------|----------------------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-mCC (15)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:40**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-mCC (16)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:40**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 16 JAN 2014 |
|------------------------------------|-------------|

---

|       |  |
|-------|--|
| Visit | Day 0 <input checked="" type="radio"/> |
|-------|--|

---

|                     |                                      |
|---------------------|--------------------------------------|
| Type of Product Use | mCC <input checked="" type="radio"/> |
|---------------------|--------------------------------------|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 15:10 |
|----------------------|-------|

---

|                     |       |
|---------------------|-------|
| Time of butt return | 15:22 |
|---------------------|-------|

---

|                |      |
|----------------|------|
| CC with SODIM? | True |
|----------------|------|

---

|                    |       |
|--------------------|-------|
| CC not compatible? | False |
|--------------------|-------|

---

|                     |     |
|---------------------|-----|
| SODIM device number | 164 |
|---------------------|-----|

---

|                            |     |
|----------------------------|-----|
| SODIM sample holder number | 207 |
|----------------------------|-----|

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10207006 |
|-------------------|----------------------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-mCC (16)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:40**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-mCC (17)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:40**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 16 JAN 2014 |
|------------------------------------|-------------|

---

|       |  |
|-------|--|
| Visit | Day 0 <input checked="" type="radio"/> |
|-------|--|

---

|                     |                                      |
|---------------------|--------------------------------------|
| Type of Product Use | mCC <input checked="" type="radio"/> |
|---------------------|--------------------------------------|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 17:17 |
|----------------------|-------|

---

|                     |       |
|---------------------|-------|
| Time of butt return | 17:25 |
|---------------------|-------|

---

|                |      |
|----------------|------|
| CC with SODIM? | True |
|----------------|------|

---

|                    |       |
|--------------------|-------|
| CC not compatible? | False |
|--------------------|-------|

---

|                     |     |
|---------------------|-----|
| SODIM device number | 164 |
|---------------------|-----|

---

|                            |     |
|----------------------------|-----|
| SODIM sample holder number | 207 |
|----------------------------|-----|

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10207007 |
|-------------------|----------------------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-mCC (17)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:40**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-mCC (18)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:40**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 16 JAN 2014 |
|------------------------------------|-------------|

---

|       |  |
|-------|--|
| Visit | Day 0 <input checked="" type="radio"/> |
|-------|--|

---

|                     |                                      |
|---------------------|--------------------------------------|
| Type of Product Use | mCC <input checked="" type="radio"/> |
|---------------------|--------------------------------------|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 18:42 |
|----------------------|-------|

---

|                     |       |
|---------------------|-------|
| Time of butt return | 18:53 |
|---------------------|-------|

---

|                |      |
|----------------|------|
| CC with SODIM? | True |
|----------------|------|

---

|                    |       |
|--------------------|-------|
| CC not compatible? | False |
|--------------------|-------|

---

|                     |     |
|---------------------|-----|
| SODIM device number | 164 |
|---------------------|-----|

---

|                            |     |
|----------------------------|-----|
| SODIM sample holder number | 207 |
|----------------------------|-----|

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10207008 |
|-------------------|----------------------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-mCC (18)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:40**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-mCC (19)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:40**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 16 JAN 2014 |
|------------------------------------|-------------|

---

|       |  |
|-------|--|
| Visit | Day 0 <input checked="" type="radio"/> |
|-------|--|

---

|                     |                                      |
|---------------------|--------------------------------------|
| Type of Product Use | mCC <input checked="" type="radio"/> |
|---------------------|--------------------------------------|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 20:49 |
|----------------------|-------|

---

|                     |       |
|---------------------|-------|
| Time of butt return | 21:01 |
|---------------------|-------|

---

|                |      |
|----------------|------|
| CC with SODIM? | True |
|----------------|------|

---

|                    |       |
|--------------------|-------|
| CC not compatible? | False |
|--------------------|-------|

---

|                     |     |
|---------------------|-----|
| SODIM device number | 164 |
|---------------------|-----|

---

|                            |     |
|----------------------------|-----|
| SODIM sample holder number | 207 |
|----------------------------|-----|

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10207009 |
|-------------------|----------------------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-mCC (19)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:40**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-mCC (20)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:40**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 16 JAN 2014 |
|------------------------------------|-------------|

---

|       |  |
|-------|--|
| Visit | Day 0 <input checked="" type="radio"/> |
|-------|--|

---

|                     |                                      |
|---------------------|--------------------------------------|
| Type of Product Use | mCC <input checked="" type="radio"/> |
|---------------------|--------------------------------------|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 21:59 |
|----------------------|-------|

---

|                     |       |
|---------------------|-------|
| Time of butt return | 22:11 |
|---------------------|-------|

---

|                |      |
|----------------|------|
| CC with SODIM? | True |
|----------------|------|

---

|                    |       |
|--------------------|-------|
| CC not compatible? | False |
|--------------------|-------|

---

|                     |     |
|---------------------|-----|
| SODIM device number | 164 |
|---------------------|-----|

---

|                            |     |
|----------------------------|-----|
| SODIM sample holder number | 207 |
|----------------------------|-----|

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10207010 |
|-------------------|----------------------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-mCC (20)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:40**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 17 JAN 2014 |
|------------------------------------|-------------|

---

|       |  |
|-------|--|
| Visit | Day 1 <input checked="" type="radio"/> |
|-------|--|

---

|                     |  |
|---------------------|--|
| Type of Product Use | THS 2.2 Menthol <input checked="" type="radio"/> |
|---------------------|--|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 07:49 |
|----------------------|-------|

---

|                        |       |
|------------------------|-------|
| Time of product return | 07:56 |
|------------------------|-------|

---

|                     |     |
|---------------------|-----|
| SODIM device number | 164 |
|---------------------|-----|

---

|                            |     |
|----------------------------|-----|
| SODIM sample holder number | 623 |
|----------------------------|-----|

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1798 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 01 |
|--------------------------|----|

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10623001 |
|-------------------|----------------------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 17 JAN 2014 |
|------------------------------------|-------------|

---

|       |  |
|-------|--|
| Visit | Day 1 <input checked="" type="radio"/> |
|-------|--|

---

|                     |  |
|---------------------|--|
| Type of Product Use | THS 2.2 Menthol <input checked="" type="radio"/> |
|---------------------|--|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 09:03 |
|----------------------|-------|

---

|                        |       |
|------------------------|-------|
| Time of product return | 09:10 |
|------------------------|-------|

---

|                     |     |
|---------------------|-----|
| SODIM device number | 164 |
|---------------------|-----|

---

|                            |     |
|----------------------------|-----|
| SODIM sample holder number | 623 |
|----------------------------|-----|

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1798 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 02 |
|--------------------------|----|

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10623002 |
|-------------------|----------------------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 17 JAN 2014 |
|------------------------------------|-------------|

---

|       |  |
|-------|--|
| Visit | Day 1 <input checked="" type="radio"/> |
|-------|--|

---

|                     |  |
|---------------------|--|
| Type of Product Use | THS 2.2 Menthol <input checked="" type="radio"/> |
|---------------------|--|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 10:45 |
|----------------------|-------|

---

|                        |       |
|------------------------|-------|
| Time of product return | 10:53 |
|------------------------|-------|

---

|                     |     |
|---------------------|-----|
| SODIM device number | 164 |
|---------------------|-----|

---

|                            |     |
|----------------------------|-----|
| SODIM sample holder number | 623 |
|----------------------------|-----|

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1798 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 03 |
|--------------------------|----|

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10623003 |
|-------------------|----------------------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 17 JAN 2014 |
|------------------------------------|-------------|

---

|       |  |
|-------|--|
| Visit | Day 1 <input checked="" type="radio"/> |
|-------|--|

---

|                     |  |
|---------------------|--|
| Type of Product Use | THS 2.2 Menthol <input checked="" type="radio"/> |
|---------------------|--|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 12:38 |
|----------------------|-------|

---

|                        |       |
|------------------------|-------|
| Time of product return | 12:45 |
|------------------------|-------|

---

|                     |     |
|---------------------|-----|
| SODIM device number | 164 |
|---------------------|-----|

---

|                            |     |
|----------------------------|-----|
| SODIM sample holder number | 623 |
|----------------------------|-----|

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1798 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 04 |
|--------------------------|----|

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10623004 |
|-------------------|----------------------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 17 JAN 2014 |
|------------------------------------|-------------|

---

|       |  |
|-------|--|
| Visit | Day 1 <input checked="" type="radio"/> |
|-------|--|

---

|                     |  |
|---------------------|--|
| Type of Product Use | THS 2.2 Menthol <input checked="" type="radio"/> |
|---------------------|--|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 13:35 |
|----------------------|-------|

---

|                        |       |
|------------------------|-------|
| Time of product return | 13:42 |
|------------------------|-------|

---

|                     |     |
|---------------------|-----|
| SODIM device number | 164 |
|---------------------|-----|

---

|                            |     |
|----------------------------|-----|
| SODIM sample holder number | 623 |
|----------------------------|-----|

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1798 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 05 |
|--------------------------|----|

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10623005 |
|-------------------|----------------------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 17 JAN 2014 |
|------------------------------------|-------------|

---

|       |  |
|-------|--|
| Visit | Day 1 <input checked="" type="radio"/> |
|-------|--|

---

|                     |  |
|---------------------|--|
| Type of Product Use | THS 2.2 Menthol <input checked="" type="radio"/> |
|---------------------|--|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 16:27 |
|----------------------|-------|

---

|                        |       |
|------------------------|-------|
| Time of product return | 16:40 |
|------------------------|-------|

---

|                     |     |
|---------------------|-----|
| SODIM device number | 164 |
|---------------------|-----|

---

|                            |     |
|----------------------------|-----|
| SODIM sample holder number | 623 |
|----------------------------|-----|

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1798 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 06 |
|--------------------------|----|

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10623006 |
|-------------------|----------------------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (7)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 17 JAN 2014 |
|------------------------------------|-------------|

---

|       |  |
|-------|--|
| Visit | Day 1 <input checked="" type="radio"/> |
|-------|--|

---

|                     |  |
|---------------------|--|
| Type of Product Use | THS 2.2 Menthol <input checked="" type="radio"/> |
|---------------------|--|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 17:24 |
|----------------------|-------|

---

|                        |       |
|------------------------|-------|
| Time of product return | 17:35 |
|------------------------|-------|

---

|                     |     |
|---------------------|-----|
| SODIM device number | 164 |
|---------------------|-----|

---

|                            |     |
|----------------------------|-----|
| SODIM sample holder number | 623 |
|----------------------------|-----|

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1798 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 07 |
|--------------------------|----|

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10623007 |
|-------------------|----------------------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (7)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (8)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 17 JAN 2014 |
|------------------------------------|-------------|

---

---

|       |  |
|-------|--|
| Visit | Day 1 <input checked="" type="radio"/> |
|-------|--|

---

---

|                     |  |
|---------------------|--|
| Type of Product Use | THS 2.2 Menthol <input checked="" type="radio"/> |
|---------------------|--|

---

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

---

|                      |       |
|----------------------|-------|
| Time of distribution | 20:12 |
|----------------------|-------|

---

---

|                        |       |
|------------------------|-------|
| Time of product return | 20:21 |
|------------------------|-------|

---

---

|                     |     |
|---------------------|-----|
| SODIM device number | 164 |
|---------------------|-----|

---

---

|                            |     |
|----------------------------|-----|
| SODIM sample holder number | 623 |
|----------------------------|-----|

---

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1798 |
|-------------------------|-------|

---

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 08 |
|--------------------------|----|

---

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10623008 |
|-------------------|----------------------|

---

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (8)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (9)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 17 JAN 2014 |
|------------------------------------|-------------|

---

|       |  |
|-------|--|
| Visit | Day 1 <input checked="" type="radio"/> |
|-------|--|

---

|                     |  |
|---------------------|--|
| Type of Product Use | THS 2.2 Menthol <input checked="" type="radio"/> |
|---------------------|--|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 20:49 |
|----------------------|-------|

---

|                        |       |
|------------------------|-------|
| Time of product return | 20:55 |
|------------------------|-------|

---

|                     |     |
|---------------------|-----|
| SODIM device number | 164 |
|---------------------|-----|

---

|                            |     |
|----------------------------|-----|
| SODIM sample holder number | 623 |
|----------------------------|-----|

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1798 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 09 |
|--------------------------|----|

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10623008 |
|-------------------|----------------------|

---

|         |   |
|---------|---|
| Comment | SUBJECT DID NOT TURN ON<br>SODIM DEVICE |
|---------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (9)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

Batch Number

B-08545

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (10)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 18 JAN 2014 |
|------------------------------------|-------------|

---

|       |  |
|-------|--|
| Visit | Day 2 <input checked="" type="radio"/> |
|-------|--|

---

|                     |  |
|---------------------|--|
| Type of Product Use | THS 2.2 Menthol <input checked="" type="radio"/> |
|---------------------|--|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 07:05 |
|----------------------|-------|

---

|                        |       |
|------------------------|-------|
| Time of product return | 07:07 |
|------------------------|-------|

---

|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1802 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 01 |
|--------------------------|----|

---

|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (10)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (11)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 18 JAN 2014 |
|------------------------------------|-------------|

---

|       |  |
|-------|--|
| Visit | Day 2 <input checked="" type="radio"/> |
|-------|--|

---

|                     |  |
|---------------------|--|
| Type of Product Use | THS 2.2 Menthol <input checked="" type="radio"/> |
|---------------------|--|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 07:22 |
|----------------------|-------|

---

|                        |       |
|------------------------|-------|
| Time of product return | 07:27 |
|------------------------|-------|

---

|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1802 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 02 |
|--------------------------|----|

---

|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (11)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (12)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 18 JAN 2014 |
|------------------------------------|-------------|

---

---

|       |                             |
|-------|-----------------------------|
| Visit | Day 2 <input type="radio"/> |
|-------|-----------------------------|

---

---

|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

---

|                      |       |
|----------------------|-------|
| Time of distribution | 08:37 |
|----------------------|-------|

---

---

|                        |       |
|------------------------|-------|
| Time of product return | 08:44 |
|------------------------|-------|

---

---

|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

---

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

---

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1802 |
|-------------------------|-------|

---

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 03 |
|--------------------------|----|

---

---

|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

---

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (12)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (13)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 18 JAN 2014 |
|------------------------------------|-------------|

---

---

|       |                             |
|-------|-----------------------------|
| Visit | Day 2 <input type="radio"/> |
|-------|-----------------------------|

---

---

|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

---

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

---

|                      |       |
|----------------------|-------|
| Time of distribution | 10:56 |
|----------------------|-------|

---

---

|                        |       |
|------------------------|-------|
| Time of product return | 11:06 |
|------------------------|-------|

---

---

|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

---

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

---

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1802 |
|-------------------------|-------|

---

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 04 |
|--------------------------|----|

---

---

|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

---

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (13)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (14)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 18 JAN 2014 |
|------------------------------------|-------------|

---

|       |  |
|-------|--|
| Visit | Day 2 <input checked="" type="radio"/> |
|-------|--|

---

|                     |  |
|---------------------|--|
| Type of Product Use | THS 2.2 Menthol <input checked="" type="radio"/> |
|---------------------|--|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 12:18 |
|----------------------|-------|

---

|                        |       |
|------------------------|-------|
| Time of product return | 12:24 |
|------------------------|-------|

---

|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1802 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 05 |
|--------------------------|----|

---

|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (14)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (15)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 18 JAN 2014 |
|------------------------------------|-------------|

---

---

|       |  |
|-------|--|
| Visit | Day 2 <input checked="" type="radio"/> |
|-------|--|

---

---

|                     |  |
|---------------------|--|
| Type of Product Use | THS 2.2 Menthol <input checked="" type="radio"/> |
|---------------------|--|

---

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

---

|                      |       |
|----------------------|-------|
| Time of distribution | 13:16 |
|----------------------|-------|

---

---

|                        |       |
|------------------------|-------|
| Time of product return | 13:23 |
|------------------------|-------|

---

---

|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

---

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

---

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1802 |
|-------------------------|-------|

---

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 06 |
|--------------------------|----|

---

---

|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

---

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (15)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (16)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 18 JAN 2014 |
|------------------------------------|-------------|

---

---

|       |  |
|-------|--|
| Visit | Day 2 <input checked="" type="radio"/> |
|-------|--|

---

---

|                     |  |
|---------------------|--|
| Type of Product Use | THS 2.2 Menthol <input checked="" type="radio"/> |
|---------------------|--|

---

If type of Product Use different from the randomization  
please explain

---

---

|                      |       |
|----------------------|-------|
| Time of distribution | 14:00 |
|----------------------|-------|

---

---

|                        |       |
|------------------------|-------|
| Time of product return | 14:13 |
|------------------------|-------|

---

---

|                     |  |
|---------------------|--|
| SODIM device number |  |
|---------------------|--|

---

---

|                            |  |
|----------------------------|--|
| SODIM sample holder number |  |
|----------------------------|--|

---

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1802 |
|-------------------------|-------|

---

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 07 |
|--------------------------|----|

---

---

|                   |  |
|-------------------|--|
| SODIM file number |  |
|-------------------|--|

---

---

|         |  |
|---------|--|
| Comment |  |
|---------|--|

---

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (16)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (17)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 18 JAN 2014 |
|------------------------------------|-------------|

---

|       |  |
|-------|--|
| Visit | Day 2 <input checked="" type="radio"/> |
|-------|--|

---

|                     |  |
|---------------------|--|
| Type of Product Use | THS 2.2 Menthol <input checked="" type="radio"/> |
|---------------------|--|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 15:20 |
|----------------------|-------|

---

|                        |       |
|------------------------|-------|
| Time of product return | 15:28 |
|------------------------|-------|

---

|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1802 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 08 |
|--------------------------|----|

---

|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (17)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (18)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 18 JAN 2014 |
|------------------------------------|-------------|

---

|       |  |
|-------|--|
| Visit | Day 2 <input checked="" type="radio"/> |
|-------|--|

---

|                     |  |
|---------------------|--|
| Type of Product Use | THS 2.2 Menthol <input checked="" type="radio"/> |
|---------------------|--|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 18:21 |
|----------------------|-------|

---

|                        |       |
|------------------------|-------|
| Time of product return | 18:27 |
|------------------------|-------|

---

|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1802 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 09 |
|--------------------------|----|

---

|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (18)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (19)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 18 JAN 2014 |
|------------------------------------|-------------|

---

---

|       |  |
|-------|--|
| Visit | Day 2 <input checked="" type="radio"/> |
|-------|--|

---

---

|                     |  |
|---------------------|--|
| Type of Product Use | THS 2.2 Menthol <input checked="" type="radio"/> |
|---------------------|--|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

---

|                      |       |
|----------------------|-------|
| Time of distribution | 19:23 |
|----------------------|-------|

---

---

|                        |       |
|------------------------|-------|
| Time of product return | 19:33 |
|------------------------|-------|

---

---

|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

---

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

---

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1802 |
|-------------------------|-------|

---

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 10 |
|--------------------------|----|

---

---

|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

---

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (19)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (20)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 18 JAN 2014 |
|------------------------------------|-------------|

---

|       |  |
|-------|--|
| Visit | Day 2 <input checked="" type="radio"/> |
|-------|--|

---

|                     |  |
|---------------------|--|
| Type of Product Use | THS 2.2 Menthol <input checked="" type="radio"/> |
|---------------------|--|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 20:39 |
|----------------------|-------|

---

|                        |       |
|------------------------|-------|
| Time of product return | 20:46 |
|------------------------|-------|

---

|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1802 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 11 |
|--------------------------|----|

---

|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (20)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (21)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 19 JAN 2014 |
|------------------------------------|-------------|

---

|       |                             |
|-------|-----------------------------|
| Visit | Day 3 <input type="radio"/> |
|-------|-----------------------------|

---

|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 06:53 |
|----------------------|-------|

---

|                        |       |
|------------------------|-------|
| Time of product return | 06:58 |
|------------------------|-------|

---

|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1806 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 01 |
|--------------------------|----|

---

|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (21)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (22)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 19 JAN 2014 |
|------------------------------------|-------------|

---

---

|       |                             |
|-------|-----------------------------|
| Visit | Day 3 <input type="radio"/> |
|-------|-----------------------------|

---

---

|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

---

|                      |       |
|----------------------|-------|
| Time of distribution | 08:16 |
|----------------------|-------|

---

---

|                        |       |
|------------------------|-------|
| Time of product return | 08:26 |
|------------------------|-------|

---

---

|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

---

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

---

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1806 |
|-------------------------|-------|

---

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 02 |
|--------------------------|----|

---

---

|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

---

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (22)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (23)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 19 JAN 2014 |
|------------------------------------|-------------|

---

|       |                             |
|-------|-----------------------------|
| Visit | Day 3 <input type="radio"/> |
|-------|-----------------------------|

---

|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 09:53 |
|----------------------|-------|

---

|                        |       |
|------------------------|-------|
| Time of product return | 10:04 |
|------------------------|-------|

---

|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1806 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 03 |
|--------------------------|----|

---

|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (23)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (24)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 19 JAN 2014 |
|------------------------------------|-------------|

---

---

|       |                             |
|-------|-----------------------------|
| Visit | Day 3 <input type="radio"/> |
|-------|-----------------------------|

---

---

|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

---

|                      |       |
|----------------------|-------|
| Time of distribution | 11:48 |
|----------------------|-------|

---

---

|                        |       |
|------------------------|-------|
| Time of product return | 11:57 |
|------------------------|-------|

---

---

|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

---

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

---

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1806 |
|-------------------------|-------|

---

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 04 |
|--------------------------|----|

---

---

|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

---

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (24)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (25)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 19 JAN 2014 |
|------------------------------------|-------------|

---

---

|       |                             |
|-------|-----------------------------|
| Visit | Day 3 <input type="radio"/> |
|-------|-----------------------------|

---

---

|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

---

If type of Product Use different from the randomization  
please explain

---

---

|                      |       |
|----------------------|-------|
| Time of distribution | 13:27 |
|----------------------|-------|

---

---

|                        |       |
|------------------------|-------|
| Time of product return | 13:35 |
|------------------------|-------|

---

---

|                     |       |
|---------------------|-------|
| SODIM device number | <hr/> |
|---------------------|-------|

---

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | <hr/> |
|----------------------------|-------|

---

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1806 |
|-------------------------|-------|

---

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 05 |
|--------------------------|----|

---

---

|                   |       |
|-------------------|-------|
| SODIM file number | <hr/> |
|-------------------|-------|

---

---

|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

---

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (25)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (26)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 19 JAN 2014 |
|------------------------------------|-------------|

---

|       |                             |
|-------|-----------------------------|
| Visit | Day 3 <input type="radio"/> |
|-------|-----------------------------|

---

|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

---

If type of Product Use different from the randomization  
please explain

---

|                      |       |
|----------------------|-------|
| Time of distribution | 14:38 |
|----------------------|-------|

---

|                        |       |
|------------------------|-------|
| Time of product return | 14:55 |
|------------------------|-------|

---

|                     |       |
|---------------------|-------|
| SODIM device number | <hr/> |
|---------------------|-------|

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | <hr/> |
|----------------------------|-------|

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1806 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 06 |
|--------------------------|----|

---

|                   |       |
|-------------------|-------|
| SODIM file number | <hr/> |
|-------------------|-------|

---

|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (26)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (27)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 19 JAN 2014 |
|------------------------------------|-------------|

---

---

|       |                             |
|-------|-----------------------------|
| Visit | Day 3 <input type="radio"/> |
|-------|-----------------------------|

---

---

|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

---

If type of Product Use different from the randomization  
please explain

---

---

|                      |       |
|----------------------|-------|
| Time of distribution | 16:30 |
|----------------------|-------|

---

---

|                        |       |
|------------------------|-------|
| Time of product return | 16:36 |
|------------------------|-------|

---

---

|                     |       |
|---------------------|-------|
| SODIM device number | <hr/> |
|---------------------|-------|

---

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | <hr/> |
|----------------------------|-------|

---

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1806 |
|-------------------------|-------|

---

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 07 |
|--------------------------|----|

---

---

|                   |       |
|-------------------|-------|
| SODIM file number | <hr/> |
|-------------------|-------|

---

---

|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

---

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (27)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (28)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 19 JAN 2014 |
|------------------------------------|-------------|

---

---

|       |                             |
|-------|-----------------------------|
| Visit | Day 3 <input type="radio"/> |
|-------|-----------------------------|

---

---

|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

---

---

If type of Product Use different from the randomization  
please explain

---

---

|                      |       |
|----------------------|-------|
| Time of distribution | 17:49 |
|----------------------|-------|

---

---

|                        |       |
|------------------------|-------|
| Time of product return | 17:57 |
|------------------------|-------|

---

---

|                     |  |
|---------------------|--|
| SODIM device number |  |
|---------------------|--|

---

---

|                            |  |
|----------------------------|--|
| SODIM sample holder number |  |
|----------------------------|--|

---

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1806 |
|-------------------------|-------|

---

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 08 |
|--------------------------|----|

---

---

|                   |  |
|-------------------|--|
| SODIM file number |  |
|-------------------|--|

---

---

|         |  |
|---------|--|
| Comment |  |
|---------|--|

---

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (28)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (29)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 19 JAN 2014 |
|------------------------------------|-------------|

---

---

|       |                             |
|-------|-----------------------------|
| Visit | Day 3 <input type="radio"/> |
|-------|-----------------------------|

---

---

|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

---

If type of Product Use different from the randomization  
please explain

---

---

|                      |       |
|----------------------|-------|
| Time of distribution | 18:05 |
|----------------------|-------|

---

---

|                        |       |
|------------------------|-------|
| Time of product return | 18:14 |
|------------------------|-------|

---

---

|                     |       |
|---------------------|-------|
| SODIM device number | <hr/> |
|---------------------|-------|

---

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | <hr/> |
|----------------------------|-------|

---

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1806 |
|-------------------------|-------|

---

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 09 |
|--------------------------|----|

---

---

|                   |       |
|-------------------|-------|
| SODIM file number | <hr/> |
|-------------------|-------|

---

---

|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

---

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (29)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (30)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 19 JAN 2014 |
|------------------------------------|-------------|

---

|       |                             |
|-------|-----------------------------|
| Visit | Day 3 <input type="radio"/> |
|-------|-----------------------------|

---

|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 20:12 |
|----------------------|-------|

---

|                        |       |
|------------------------|-------|
| Time of product return | 20:18 |
|------------------------|-------|

---

|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1806 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 10 |
|--------------------------|----|

---

|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (30)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (31)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 20 JAN 2014 |
|------------------------------------|-------------|

---

|       |                             |
|-------|-----------------------------|
| Visit | Day 4 <input type="radio"/> |
|-------|-----------------------------|

---

|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 06:55 |
|----------------------|-------|

---

|                        |       |
|------------------------|-------|
| Time of product return | 07:01 |
|------------------------|-------|

---

|                     |     |
|---------------------|-----|
| SODIM device number | 164 |
|---------------------|-----|

---

|                            |     |
|----------------------------|-----|
| SODIM sample holder number | 623 |
|----------------------------|-----|

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1815 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 01 |
|--------------------------|----|

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10623009 |
|-------------------|----------------------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (31)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (32)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 20 JAN 2014 |
|------------------------------------|-------------|

---

|       |                             |
|-------|-----------------------------|
| Visit | Day 4 <input type="radio"/> |
|-------|-----------------------------|

---

|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 07:36 |
|----------------------|-------|

---

|                        |       |
|------------------------|-------|
| Time of product return | 07:46 |
|------------------------|-------|

---

|                     |     |
|---------------------|-----|
| SODIM device number | 164 |
|---------------------|-----|

---

|                            |     |
|----------------------------|-----|
| SODIM sample holder number | 623 |
|----------------------------|-----|

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1815 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 02 |
|--------------------------|----|

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10623010 |
|-------------------|----------------------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (32)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (33)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 20 JAN 2014 |
|------------------------------------|-------------|

---

---

|       |                             |
|-------|-----------------------------|
| Visit | Day 4 <input type="radio"/> |
|-------|-----------------------------|

---

---

|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

---

If type of Product Use different from the randomization  
please explain

---

---

|                      |       |
|----------------------|-------|
| Time of distribution | 09:20 |
|----------------------|-------|

---

---

|                        |       |
|------------------------|-------|
| Time of product return | 09:28 |
|------------------------|-------|

---

---

|                     |     |
|---------------------|-----|
| SODIM device number | 164 |
|---------------------|-----|

---

---

|                            |     |
|----------------------------|-----|
| SODIM sample holder number | 623 |
|----------------------------|-----|

---

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1815 |
|-------------------------|-------|

---

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 03 |
|--------------------------|----|

---

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10623011 |
|-------------------|----------------------|

---

---

|         |  |
|---------|--|
| Comment |  |
|---------|--|

---

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (33)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (34)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 20 JAN 2014 |
|------------------------------------|-------------|

---

---

|       |                             |
|-------|-----------------------------|
| Visit | Day 4 <input type="radio"/> |
|-------|-----------------------------|

---

---

|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

---

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

---

|                      |       |
|----------------------|-------|
| Time of distribution | 11:21 |
|----------------------|-------|

---

---

|                        |       |
|------------------------|-------|
| Time of product return | 11:28 |
|------------------------|-------|

---

---

|                     |     |
|---------------------|-----|
| SODIM device number | 164 |
|---------------------|-----|

---

---

|                            |     |
|----------------------------|-----|
| SODIM sample holder number | 623 |
|----------------------------|-----|

---

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1815 |
|-------------------------|-------|

---

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 04 |
|--------------------------|----|

---

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10623012 |
|-------------------|----------------------|

---

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (34)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (35)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 20 JAN 2014 |
|------------------------------------|-------------|

---

|       |                             |
|-------|-----------------------------|
| Visit | Day 4 <input type="radio"/> |
|-------|-----------------------------|

---

|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 12:17 |
|----------------------|-------|

---

|                        |       |
|------------------------|-------|
| Time of product return | 12:25 |
|------------------------|-------|

---

|                     |     |
|---------------------|-----|
| SODIM device number | 164 |
|---------------------|-----|

---

|                            |     |
|----------------------------|-----|
| SODIM sample holder number | 623 |
|----------------------------|-----|

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1815 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 05 |
|--------------------------|----|

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10623013 |
|-------------------|----------------------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (35)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (36)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 20 JAN 2014 |
|------------------------------------|-------------|

---

|       |  |
|-------|--|
| Visit | Day 4 <input checked="" type="radio"/> |
|-------|--|

---

|                     |  |
|---------------------|--|
| Type of Product Use | THS 2.2 Menthol <input checked="" type="radio"/> |
|---------------------|--|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 13:43 |
|----------------------|-------|

---

|                        |       |
|------------------------|-------|
| Time of product return | 13:50 |
|------------------------|-------|

---

|                     |     |
|---------------------|-----|
| SODIM device number | 164 |
|---------------------|-----|

---

|                            |     |
|----------------------------|-----|
| SODIM sample holder number | 623 |
|----------------------------|-----|

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1815 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 06 |
|--------------------------|----|

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10623014 |
|-------------------|----------------------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (36)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (37)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 20 JAN 2014 |
|------------------------------------|-------------|

---

|       |                             |
|-------|-----------------------------|
| Visit | Day 4 <input type="radio"/> |
|-------|-----------------------------|

---

|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 16:16 |
|----------------------|-------|

---

|                        |       |
|------------------------|-------|
| Time of product return | 16:25 |
|------------------------|-------|

---

|                     |     |
|---------------------|-----|
| SODIM device number | 164 |
|---------------------|-----|

---

|                            |     |
|----------------------------|-----|
| SODIM sample holder number | 623 |
|----------------------------|-----|

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1815 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 07 |
|--------------------------|----|

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10623015 |
|-------------------|----------------------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (37)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (38)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 20 JAN 2014 |
|------------------------------------|-------------|

---

|       |  |
|-------|--|
| Visit | Day 4 <input checked="" type="radio"/> |
|-------|--|

---

|                     |  |
|---------------------|--|
| Type of Product Use | THS 2.2 Menthol <input checked="" type="radio"/> |
|---------------------|--|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 16:35 |
|----------------------|-------|

---

|                        |       |
|------------------------|-------|
| Time of product return | 16:38 |
|------------------------|-------|

---

|                     |     |
|---------------------|-----|
| SODIM device number | 164 |
|---------------------|-----|

---

|                            |     |
|----------------------------|-----|
| SODIM sample holder number | 623 |
|----------------------------|-----|

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1815 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 08 |
|--------------------------|----|

---

|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

---

|         |   |
|---------|---|
| Comment | THS STICK DESTROYED DUE<br>TO MALFUNCTIONING<br>HOLDER. |
|---------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (38)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

Batch Number

B-08545

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (39)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 20 JAN 2014 |
|------------------------------------|-------------|

---

|       |                             |
|-------|-----------------------------|
| Visit | Day 4 <input type="radio"/> |
|-------|-----------------------------|

---

|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 16:40 |
|----------------------|-------|

---

|                        |       |
|------------------------|-------|
| Time of product return | 16:48 |
|------------------------|-------|

---

|                     |     |
|---------------------|-----|
| SODIM device number | 164 |
|---------------------|-----|

---

|                            |     |
|----------------------------|-----|
| SODIM sample holder number | 623 |
|----------------------------|-----|

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1815 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 09 |
|--------------------------|----|

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10623016 |
|-------------------|----------------------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (39)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (40)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 20 JAN 2014 |
|------------------------------------|-------------|

---

---

|       |                             |
|-------|-----------------------------|
| Visit | Day 4 <input type="radio"/> |
|-------|-----------------------------|

---

---

|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

---

|                      |       |
|----------------------|-------|
| Time of distribution | 18:08 |
|----------------------|-------|

---

---

|                        |       |
|------------------------|-------|
| Time of product return | 18:17 |
|------------------------|-------|

---

---

|                     |     |
|---------------------|-----|
| SODIM device number | 164 |
|---------------------|-----|

---

---

|                            |     |
|----------------------------|-----|
| SODIM sample holder number | 623 |
|----------------------------|-----|

---

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1815 |
|-------------------------|-------|

---

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 10 |
|--------------------------|----|

---

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10623016 |
|-------------------|----------------------|

---

---

|         |  |
|---------|--|
| Comment | MACHINE TURNED OFF<br>DURING SMOKING EVENT |
|---------|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (40)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

Batch Number

B-08545

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (41)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 20 JAN 2014 |
|------------------------------------|-------------|

---

|       |                             |
|-------|-----------------------------|
| Visit | Day 4 <input type="radio"/> |
|-------|-----------------------------|

---

|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 19:36 |
|----------------------|-------|

---

|                        |       |
|------------------------|-------|
| Time of product return | 19:43 |
|------------------------|-------|

---

|                     |     |
|---------------------|-----|
| SODIM device number | 164 |
|---------------------|-----|

---

|                            |     |
|----------------------------|-----|
| SODIM sample holder number | 623 |
|----------------------------|-----|

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1815 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 11 |
|--------------------------|----|

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10623017 |
|-------------------|----------------------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (41)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (42)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 20 JAN 2014 |
|------------------------------------|-------------|

---

|       |                             |
|-------|-----------------------------|
| Visit | Day 4 <input type="radio"/> |
|-------|-----------------------------|

---

|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 20:47 |
|----------------------|-------|

---

|                        |       |
|------------------------|-------|
| Time of product return | 20:54 |
|------------------------|-------|

---

|                     |     |
|---------------------|-----|
| SODIM device number | 164 |
|---------------------|-----|

---

|                            |     |
|----------------------------|-----|
| SODIM sample holder number | 623 |
|----------------------------|-----|

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1815 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 12 |
|--------------------------|----|

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10623017 |
|-------------------|----------------------|

---

|         |  |
|---------|--|
| Comment | MACHINE TURNED OFF<br>DURING SMOKING EVENT |
|---------|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (42)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

Batch Number

B-08545

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (43)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 21 JAN 2014 |
|------------------------------------|-------------|

---

|       |                             |
|-------|-----------------------------|
| Visit | Day 5 <input type="radio"/> |
|-------|-----------------------------|

---

|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 06:54 |
|----------------------|-------|

---

|                        |       |
|------------------------|-------|
| Time of product return | 07:02 |
|------------------------|-------|

---

|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1818 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 01 |
|--------------------------|----|

---

|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (43)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (44)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 21 JAN 2014 |
|------------------------------------|-------------|

---

|       |                             |
|-------|-----------------------------|
| Visit | Day 5 <input type="radio"/> |
|-------|-----------------------------|

---

|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 07:44 |
|----------------------|-------|

---

|                        |       |
|------------------------|-------|
| Time of product return | 07:50 |
|------------------------|-------|

---

|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1818 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 02 |
|--------------------------|----|

---

|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (44)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (45)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 21 JAN 2014 |
|------------------------------------|-------------|

---

---

|       |                             |
|-------|-----------------------------|
| Visit | Day 5 <input type="radio"/> |
|-------|-----------------------------|

---

---

|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

---

If type of Product Use different from the randomization  
please explain

---

---

|                      |       |
|----------------------|-------|
| Time of distribution | 09:51 |
|----------------------|-------|

---

---

|                        |       |
|------------------------|-------|
| Time of product return | 10:00 |
|------------------------|-------|

---

---

|                     |       |
|---------------------|-------|
| SODIM device number | <hr/> |
|---------------------|-------|

---

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | <hr/> |
|----------------------------|-------|

---

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1818 |
|-------------------------|-------|

---

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 03 |
|--------------------------|----|

---

---

|                   |       |
|-------------------|-------|
| SODIM file number | <hr/> |
|-------------------|-------|

---

---

|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

---

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (45)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (46)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 21 JAN 2014 |
|------------------------------------|-------------|

---

|       |                             |
|-------|-----------------------------|
| Visit | Day 5 <input type="radio"/> |
|-------|-----------------------------|

---

|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 10:31 |
|----------------------|-------|

---

|                        |       |
|------------------------|-------|
| Time of product return | 10:38 |
|------------------------|-------|

---

|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1818 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 04 |
|--------------------------|----|

---

|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (46)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (47)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 21 JAN 2014 |
|------------------------------------|-------------|

---

|       |                             |
|-------|-----------------------------|
| Visit | Day 5 <input type="radio"/> |
|-------|-----------------------------|

---

|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 11:25 |
|----------------------|-------|

---

|                        |       |
|------------------------|-------|
| Time of product return | 11:38 |
|------------------------|-------|

---

|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1818 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 05 |
|--------------------------|----|

---

|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (47)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (48)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 21 JAN 2014 |
|------------------------------------|-------------|

---

|       |                             |
|-------|-----------------------------|
| Visit | Day 5 <input type="radio"/> |
|-------|-----------------------------|

---

|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 12:21 |
|----------------------|-------|

---

|                        |       |
|------------------------|-------|
| Time of product return | 12:30 |
|------------------------|-------|

---

|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1818 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 06 |
|--------------------------|----|

---

|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (48)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (49)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 21 JAN 2014 |
|------------------------------------|-------------|

---

|       |                             |
|-------|-----------------------------|
| Visit | Day 5 <input type="radio"/> |
|-------|-----------------------------|

---

|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 14:14 |
|----------------------|-------|

---

|                        |       |
|------------------------|-------|
| Time of product return | 14:21 |
|------------------------|-------|

---

|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1818 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 07 |
|--------------------------|----|

---

|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (49)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (50)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 21 JAN 2014 |
|------------------------------------|-------------|

---

---

|       |                             |
|-------|-----------------------------|
| Visit | Day 5 <input type="radio"/> |
|-------|-----------------------------|

---

---

|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

---

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

---

|                      |       |
|----------------------|-------|
| Time of distribution | 14:56 |
|----------------------|-------|

---

---

|                        |       |
|------------------------|-------|
| Time of product return | 15:08 |
|------------------------|-------|

---

---

|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

---

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

---

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1818 |
|-------------------------|-------|

---

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 08 |
|--------------------------|----|

---

---

|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

---

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (50)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (51)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 21 JAN 2014 |
|------------------------------------|-------------|

---

|       |                             |
|-------|-----------------------------|
| Visit | Day 5 <input type="radio"/> |
|-------|-----------------------------|

---

|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 15:21 |
|----------------------|-------|

---

|                        |       |
|------------------------|-------|
| Time of product return | 15:30 |
|------------------------|-------|

---

|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1818 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 09 |
|--------------------------|----|

---

|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (51)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (52)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 21 JAN 2014 |
|------------------------------------|-------------|

---

|       |                             |
|-------|-----------------------------|
| Visit | Day 5 <input type="radio"/> |
|-------|-----------------------------|

---

|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 16:51 |
|----------------------|-------|

---

|                        |       |
|------------------------|-------|
| Time of product return | 17:03 |
|------------------------|-------|

---

|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1818 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 10 |
|--------------------------|----|

---

|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (52)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (53)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 21 JAN 2014 |
|------------------------------------|-------------|

---

|       |                             |
|-------|-----------------------------|
| Visit | Day 5 <input type="radio"/> |
|-------|-----------------------------|

---

|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 18:51 |
|----------------------|-------|

---

|                        |       |
|------------------------|-------|
| Time of product return | 18:58 |
|------------------------|-------|

---

|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1818 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 11 |
|--------------------------|----|

---

|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (53)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (54)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 21 JAN 2014 |
|------------------------------------|-------------|

---

|       |                             |
|-------|-----------------------------|
| Visit | Day 5 <input type="radio"/> |
|-------|-----------------------------|

---

|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 20:00 |
|----------------------|-------|

---

|                        |       |
|------------------------|-------|
| Time of product return | 20:09 |
|------------------------|-------|

---

|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1818 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 12 |
|--------------------------|----|

---

|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (54)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (55)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 21 JAN 2014 |
|------------------------------------|-------------|

---

|       |                             |
|-------|-----------------------------|
| Visit | Day 5 <input type="radio"/> |
|-------|-----------------------------|

---

|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

---

|                      |       |
|----------------------|-------|
| Time of distribution | 21:04 |
|----------------------|-------|

---

|                        |       |
|------------------------|-------|
| Time of product return | 21:14 |
|------------------------|-------|

---

|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1818 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 13 |
|--------------------------|----|

---

|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (55)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (56)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 21 JAN 2014 |
|------------------------------------|-------------|

---

|       |                             |
|-------|-----------------------------|
| Visit | Day 5 <input type="radio"/> |
|-------|-----------------------------|

---

|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

---

If type of Product Use different from the randomization  
please explain

---

|                      |       |
|----------------------|-------|
| Time of distribution | 21:27 |
|----------------------|-------|

---

|                        |       |
|------------------------|-------|
| Time of product return | 21:38 |
|------------------------|-------|

---

|                     |       |
|---------------------|-------|
| SODIM device number | <hr/> |
|---------------------|-------|

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | <hr/> |
|----------------------------|-------|

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1818 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 14 |
|--------------------------|----|

---

|                   |       |
|-------------------|-------|
| SODIM file number | <hr/> |
|-------------------|-------|

---

|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (56)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (57)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 21 JAN 2014 |
|------------------------------------|-------------|

---

|       |                             |
|-------|-----------------------------|
| Visit | Day 5 <input type="radio"/> |
|-------|-----------------------------|

---

|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

---

If type of Product Use different from the randomization  
please explain

---

|                      |  |
|----------------------|--|
| Time of distribution |  |
|----------------------|--|

---

|                        |       |
|------------------------|-------|
| Time of product return | 22:33 |
|------------------------|-------|

---

|                     |  |
|---------------------|--|
| SODIM device number |  |
|---------------------|--|

---

|                            |  |
|----------------------------|--|
| SODIM sample holder number |  |
|----------------------------|--|

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1818 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 15 |
|--------------------------|----|

---

|                   |  |
|-------------------|--|
| SODIM file number |  |
|-------------------|--|

---

|         |  |
|---------|--|
| Comment | DISPENSE TIME NOT<br>CAPTURED AT TIME OF TASK. |
|---------|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (57)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

Batch Number

B-08545

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (58)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 22 JAN 2014 |
|------------------------------------|-------------|

---

---

|       |                             |
|-------|-----------------------------|
| Visit | Day 6 <input type="radio"/> |
|-------|-----------------------------|

---

---

|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

---

If type of Product Use different from the randomization  
please explain

---

---

|                      |       |
|----------------------|-------|
| Time of distribution | 10:46 |
|----------------------|-------|

---

---

|                        |       |
|------------------------|-------|
| Time of product return | 10:53 |
|------------------------|-------|

---

---

|                     |       |
|---------------------|-------|
| SODIM device number | <hr/> |
|---------------------|-------|

---

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | <hr/> |
|----------------------------|-------|

---

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | <hr/> |
|-------------------------|-------|

---

---

|                          |       |
|--------------------------|-------|
| Tobacco plug vial number | <hr/> |
|--------------------------|-------|

---

---

|                   |       |
|-------------------|-------|
| SODIM file number | <hr/> |
|-------------------|-------|

---

---

|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

---

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (58)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (59)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 22 JAN 2014 |
|------------------------------------|-------------|

---

---

|       |                             |
|-------|-----------------------------|
| Visit | Day 6 <input type="radio"/> |
|-------|-----------------------------|

---

---

|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

---

If type of Product Use different from the randomization  
please explain

---

---

|                      |       |
|----------------------|-------|
| Time of distribution | 11:37 |
|----------------------|-------|

---

---

|                        |       |
|------------------------|-------|
| Time of product return | 11:48 |
|------------------------|-------|

---

---

|                     |       |
|---------------------|-------|
| SODIM device number | <hr/> |
|---------------------|-------|

---

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | <hr/> |
|----------------------------|-------|

---

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | <hr/> |
|-------------------------|-------|

---

---

|                          |       |
|--------------------------|-------|
| Tobacco plug vial number | <hr/> |
|--------------------------|-------|

---

---

|                   |       |
|-------------------|-------|
| SODIM file number | <hr/> |
|-------------------|-------|

---

---

|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

---

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (59)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (60)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 22 JAN 2014 |
|------------------------------------|-------------|

---

---

|       |                             |
|-------|-----------------------------|
| Visit | Day 6 <input type="radio"/> |
|-------|-----------------------------|

---

---

|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

---

If type of Product Use different from the randomization  
please explain

---

---

|                      |       |
|----------------------|-------|
| Time of distribution | 12:46 |
|----------------------|-------|

---

---

|                        |       |
|------------------------|-------|
| Time of product return | 12:51 |
|------------------------|-------|

---

---

|                     |       |
|---------------------|-------|
| SODIM device number | <hr/> |
|---------------------|-------|

---

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | <hr/> |
|----------------------------|-------|

---

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | <hr/> |
|-------------------------|-------|

---

---

|                          |       |
|--------------------------|-------|
| Tobacco plug vial number | <hr/> |
|--------------------------|-------|

---

---

|                   |       |
|-------------------|-------|
| SODIM file number | <hr/> |
|-------------------|-------|

---

---

|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

---

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (60)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (61)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 14 JAN 2014 |
|------------------------------------|-------------|

---

---

|       |                              |
|-------|------------------------------|
| Visit | Day -2 <input type="radio"/> |
|-------|------------------------------|

---

---

|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

---

---

|   |              |
|---|--------------|
| If type of Product Use different from the randomization<br>please explain | PRODUCT TEST |
|---|--------------|

---

---

|                      |       |
|----------------------|-------|
| Time of distribution | 19:07 |
|----------------------|-------|

---

---

|                        |       |
|------------------------|-------|
| Time of product return | <hr/> |
|------------------------|-------|

---

---

|                     |       |
|---------------------|-------|
| SODIM device number | <hr/> |
|---------------------|-------|

---

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | <hr/> |
|----------------------------|-------|

---

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | <hr/> |
|-------------------------|-------|

---

---

|                          |       |
|--------------------------|-------|
| Tobacco plug vial number | <hr/> |
|--------------------------|-------|

---

---

|                   |       |
|-------------------|-------|
| SODIM file number | <hr/> |
|-------------------|-------|

---

---

|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

---

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (61)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (62)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 14 JAN 2014 |
|------------------------------------|-------------|

---

|       |                              |
|-------|------------------------------|
| Visit | Day -2 <input type="radio"/> |
|-------|------------------------------|

---

|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

---

|   |              |
|---|--------------|
| If type of Product Use different from the randomization<br>please explain | PRODUCT TEST |
|---|--------------|

---

|                      |       |
|----------------------|-------|
| Time of distribution | <hr/> |
|----------------------|-------|

---

|                        |       |
|------------------------|-------|
| Time of product return | <hr/> |
|------------------------|-------|

---

|                     |       |
|---------------------|-------|
| SODIM device number | <hr/> |
|---------------------|-------|

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | <hr/> |
|----------------------------|-------|

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | <hr/> |
|-------------------------|-------|

---

|                          |       |
|--------------------------|-------|
| Tobacco plug vial number | <hr/> |
|--------------------------|-------|

---

|                   |       |
|-------------------|-------|
| SODIM file number | <hr/> |
|-------------------|-------|

---

|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

---

|              |         |
|--------------|---------|
| Batch Number | B-08545 |
|--------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Product Use**

**Form: Product administration-THS menthol (62)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:42**

**Generated On: 20 Jul 2016 11:47:42**

---

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for mCC (1)**

**Generated On: 20 Jul 2016 11:47:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for mCC (2)**

**Generated On: 20 Jul 2016 11:47:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for mCC (3)**

**Generated On: 20 Jul 2016 11:47:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for mCC (4)**

**Generated On: 20 Jul 2016 11:47:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for mCC (5)**

**Generated On: 20 Jul 2016 11:47:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for mCC (6)**

**Generated On: 20 Jul 2016 11:47:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for mCC (7)**

**Generated On: 20 Jul 2016 11:47:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for mCC (8)**

**Generated On: 20 Jul 2016 11:47:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for mCC (9)**

**Generated On: 20 Jul 2016 11:47:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for mCC (10)**

**Generated On: 20 Jul 2016 11:47:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for mCC (11)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10207001 |
|-------------------|----------------------|

---

|             |   |
|-------------|---|
| File Status | Accepted <input checked="" type="radio"/> |
|-------------|---|

---

|                          |       |
|--------------------------|-------|
| Rejection / Error reason | <hr/> |
|--------------------------|-------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 18 AUG 2014 |
|---------------------------------|-------------|

---

|          |   |
|----------|---|
| Operator | Thierry Bachmann <input checked="" type="radio"/> |
|----------|---|

---

|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

---

|                      |       |
|----------------------|-------|
| Modified File Number | <hr/> |
|----------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for mCC (12)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10207002 |
|-------------------|----------------------|

---

|             |   |
|-------------|---|
| File Status | Accepted <input checked="" type="radio"/> |
|-------------|---|

---

|                          |       |
|--------------------------|-------|
| Rejection / Error reason | <hr/> |
|--------------------------|-------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 18 AUG 2014 |
|---------------------------------|-------------|

---

|          |   |
|----------|---|
| Operator | Thierry Bachmann <input checked="" type="radio"/> |
|----------|---|

---

|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

---

|                      |       |
|----------------------|-------|
| Modified File Number | <hr/> |
|----------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for mCC (13)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10207003 |
|-------------------|----------------------|

---

|             |   |
|-------------|---|
| File Status | Accepted <input checked="" type="radio"/> |
|-------------|---|

---

|                          |       |
|--------------------------|-------|
| Rejection / Error reason | <hr/> |
|--------------------------|-------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 18 AUG 2014 |
|---------------------------------|-------------|

---

|          |   |
|----------|---|
| Operator | Thierry Bachmann <input checked="" type="radio"/> |
|----------|---|

---

|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

---

|                      |       |
|----------------------|-------|
| Modified File Number | <hr/> |
|----------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for mCC (14)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10207004 |
|-------------------|----------------------|

---

|             |   |
|-------------|---|
| File Status | Accepted <input checked="" type="radio"/> |
|-------------|---|

---

|                          |       |
|--------------------------|-------|
| Rejection / Error reason | <hr/> |
|--------------------------|-------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 18 AUG 2014 |
|---------------------------------|-------------|

---

|          |   |
|----------|---|
| Operator | Thierry Bachmann <input checked="" type="radio"/> |
|----------|---|

---

|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

---

|                      |       |
|----------------------|-------|
| Modified File Number | <hr/> |
|----------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for mCC (15)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10207005 |
|-------------------|----------------------|

---

|             |   |
|-------------|---|
| File Status | Accepted <input checked="" type="radio"/> |
|-------------|---|

---

|                          |       |
|--------------------------|-------|
| Rejection / Error reason | <hr/> |
|--------------------------|-------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 18 AUG 2014 |
|---------------------------------|-------------|

---

|          |   |
|----------|---|
| Operator | Thierry Bachmann <input checked="" type="radio"/> |
|----------|---|

---

|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

---

|                      |       |
|----------------------|-------|
| Modified File Number | <hr/> |
|----------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for mCC (16)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10207006 |
|-------------------|----------------------|

---

|             |   |
|-------------|---|
| File Status | Accepted <input checked="" type="radio"/> |
|-------------|---|

---

|                          |       |
|--------------------------|-------|
| Rejection / Error reason | <hr/> |
|--------------------------|-------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 18 AUG 2014 |
|---------------------------------|-------------|

---

|          |   |
|----------|---|
| Operator | Thierry Bachmann <input checked="" type="radio"/> |
|----------|---|

---

|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

---

|                      |       |
|----------------------|-------|
| Modified File Number | <hr/> |
|----------------------|-------|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for mCC (17)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10207007 |
|-------------------|----------------------|

---

|             |   |
|-------------|---|
| File Status | Accepted <input checked="" type="radio"/> |
|-------------|---|

---

|                          |  |
|--------------------------|--|
| Rejection / Error reason |  |
|--------------------------|--|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 18 AUG 2014 |
|---------------------------------|-------------|

---

|          |   |
|----------|---|
| Operator | Thierry Bachmann <input checked="" type="radio"/> |
|----------|---|

---

|         |  |
|---------|--|
| Comment |  |
|---------|--|

---

|                      |  |
|----------------------|--|
| Modified File Number |  |
|----------------------|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for mCC (18)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10207008 |
|-------------------|----------------------|

---

|             |   |
|-------------|---|
| File Status | Accepted <input checked="" type="radio"/> |
|-------------|---|

---

|                          |       |
|--------------------------|-------|
| Rejection / Error reason | <hr/> |
|--------------------------|-------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 18 AUG 2014 |
|---------------------------------|-------------|

---

|          |   |
|----------|---|
| Operator | Thierry Bachmann <input checked="" type="radio"/> |
|----------|---|

---

|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

---

|                      |       |
|----------------------|-------|
| Modified File Number | <hr/> |
|----------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for mCC (19)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10207009 |
|-------------------|----------------------|

---

|             |   |
|-------------|---|
| File Status | Accepted <input checked="" type="radio"/> |
|-------------|---|

---

|                          |       |
|--------------------------|-------|
| Rejection / Error reason | <hr/> |
|--------------------------|-------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 18 AUG 2014 |
|---------------------------------|-------------|

---

|          |   |
|----------|---|
| Operator | Thierry Bachmann <input checked="" type="radio"/> |
|----------|---|

---

|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

---

|                      |       |
|----------------------|-------|
| Modified File Number | <hr/> |
|----------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for mCC (20)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10207010 |
|-------------------|----------------------|

---

|             |   |
|-------------|---|
| File Status | Accepted <input checked="" type="radio"/> |
|-------------|---|

---

|                          |       |
|--------------------------|-------|
| Rejection / Error reason | <hr/> |
|--------------------------|-------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 18 AUG 2014 |
|---------------------------------|-------------|

---

|          |   |
|----------|---|
| Operator | Thierry Bachmann <input checked="" type="radio"/> |
|----------|---|

---

|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

---

|                      |       |
|----------------------|-------|
| Modified File Number | <hr/> |
|----------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (1)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10623001 |
|-------------------|----------------------|

---

|             |   |
|-------------|---|
| File Status | Accepted <input checked="" type="radio"/> |
|-------------|---|

---

|                          |       |
|--------------------------|-------|
| Rejection / Error reason | <hr/> |
|--------------------------|-------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 18 AUG 2014 |
|---------------------------------|-------------|

---

|          |   |
|----------|---|
| Operator | Thierry Bachmann <input checked="" type="radio"/> |
|----------|---|

---

|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

---

|                      |       |
|----------------------|-------|
| Modified File Number | <hr/> |
|----------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (2)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10623002 |
|-------------------|----------------------|

---

|             |   |
|-------------|---|
| File Status | Accepted <input checked="" type="radio"/> |
|-------------|---|

---

|                          |       |
|--------------------------|-------|
| Rejection / Error reason | <hr/> |
|--------------------------|-------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 18 AUG 2014 |
|---------------------------------|-------------|

---

|          |   |
|----------|---|
| Operator | Thierry Bachmann <input checked="" type="radio"/> |
|----------|---|

---

|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

---

|                      |       |
|----------------------|-------|
| Modified File Number | <hr/> |
|----------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (3)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10623003 |
|-------------------|----------------------|

---

|             |   |
|-------------|---|
| File Status | Accepted <input checked="" type="radio"/> |
|-------------|---|

---

|                          |       |
|--------------------------|-------|
| Rejection / Error reason | <hr/> |
|--------------------------|-------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 18 AUG 2014 |
|---------------------------------|-------------|

---

|          |   |
|----------|---|
| Operator | Thierry Bachmann <input checked="" type="radio"/> |
|----------|---|

---

|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

---

|                      |       |
|----------------------|-------|
| Modified File Number | <hr/> |
|----------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (4)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10623004 |
|-------------------|----------------------|

---

|             |   |
|-------------|---|
| File Status | Accepted <input checked="" type="radio"/> |
|-------------|---|

---

|                          |       |
|--------------------------|-------|
| Rejection / Error reason | <hr/> |
|--------------------------|-------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 18 AUG 2014 |
|---------------------------------|-------------|

---

|          |   |
|----------|---|
| Operator | Thierry Bachmann <input checked="" type="radio"/> |
|----------|---|

---

|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

---

|                      |       |
|----------------------|-------|
| Modified File Number | <hr/> |
|----------------------|-------|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (5)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10623005 |
|-------------------|----------------------|

---

|             |   |
|-------------|---|
| File Status | Accepted <input checked="" type="radio"/> |
|-------------|---|

---

|                          |       |
|--------------------------|-------|
| Rejection / Error reason | <hr/> |
|--------------------------|-------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 18 AUG 2014 |
|---------------------------------|-------------|

---

|          |   |
|----------|---|
| Operator | Thierry Bachmann <input checked="" type="radio"/> |
|----------|---|

---

|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

---

|                      |       |
|----------------------|-------|
| Modified File Number | <hr/> |
|----------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (6)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10623006 |
|-------------------|----------------------|

---

|             |   |
|-------------|---|
| File Status | Accepted <input checked="" type="radio"/> |
|-------------|---|

---

|                          |       |
|--------------------------|-------|
| Rejection / Error reason | <hr/> |
|--------------------------|-------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 18 AUG 2014 |
|---------------------------------|-------------|

---

|          |   |
|----------|---|
| Operator | Thierry Bachmann <input checked="" type="radio"/> |
|----------|---|

---

|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

---

|                      |       |
|----------------------|-------|
| Modified File Number | <hr/> |
|----------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (7)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10623007 |
|-------------------|----------------------|

---

|             |   |
|-------------|---|
| File Status | Accepted <input checked="" type="radio"/> |
|-------------|---|

---

|                          |       |
|--------------------------|-------|
| Rejection / Error reason | <hr/> |
|--------------------------|-------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 18 AUG 2014 |
|---------------------------------|-------------|

---

|          |   |
|----------|---|
| Operator | Thierry Bachmann <input checked="" type="radio"/> |
|----------|---|

---

|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

---

|                      |       |
|----------------------|-------|
| Modified File Number | <hr/> |
|----------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (10)**

**Generated On: 20 Jul 2016 11:47:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (11)**

**Generated On: 20 Jul 2016 11:47:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (12)**

**Generated On: 20 Jul 2016 11:47:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (13)**

**Generated On: 20 Jul 2016 11:47:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (14)**

**Generated On: 20 Jul 2016 11:47:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (15)**

**Generated On: 20 Jul 2016 11:47:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (16)**

**Generated On: 20 Jul 2016 11:47:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (17)**

**Generated On: 20 Jul 2016 11:47:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (18)**

**Generated On: 20 Jul 2016 11:47:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (19)**

**Generated On: 20 Jul 2016 11:47:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (20)**

**Generated On: 20 Jul 2016 11:47:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (21)**

**Generated On: 20 Jul 2016 11:47:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (22)**

**Generated On: 20 Jul 2016 11:47:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (23)**

**Generated On: 20 Jul 2016 11:47:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (24)**

**Generated On: 20 Jul 2016 11:47:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (25)**

**Generated On: 20 Jul 2016 11:47:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (26)**

**Generated On: 20 Jul 2016 11:47:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (27)**

**Generated On: 20 Jul 2016 11:47:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (28)**

**Generated On: 20 Jul 2016 11:47:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (29)**

**Generated On: 20 Jul 2016 11:47:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (30)**

**Generated On: 20 Jul 2016 11:47:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (31)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10623009 |
|-------------------|----------------------|

---

|             |   |
|-------------|---|
| File Status | Accepted <input checked="" type="radio"/> |
|-------------|---|

---

|                          |       |
|--------------------------|-------|
| Rejection / Error reason | <hr/> |
|--------------------------|-------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 18 AUG 2014 |
|---------------------------------|-------------|

---

|          |   |
|----------|---|
| Operator | Thierry Bachmann <input checked="" type="radio"/> |
|----------|---|

---

|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

---

|                      |       |
|----------------------|-------|
| Modified File Number | <hr/> |
|----------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (32)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10623010 |
|-------------------|----------------------|

---

|             |   |
|-------------|---|
| File Status | Accepted <input checked="" type="radio"/> |
|-------------|---|

---

|                          |       |
|--------------------------|-------|
| Rejection / Error reason | <hr/> |
|--------------------------|-------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 18 AUG 2014 |
|---------------------------------|-------------|

---

|          |   |
|----------|---|
| Operator | Thierry Bachmann <input checked="" type="radio"/> |
|----------|---|

---

|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

---

|                      |       |
|----------------------|-------|
| Modified File Number | <hr/> |
|----------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (33)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10623011 |
|-------------------|----------------------|

---

|             |   |
|-------------|---|
| File Status | Accepted <input checked="" type="radio"/> |
|-------------|---|

---

|                          |       |
|--------------------------|-------|
| Rejection / Error reason | <hr/> |
|--------------------------|-------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 18 AUG 2014 |
|---------------------------------|-------------|

---

|          |   |
|----------|---|
| Operator | Thierry Bachmann <input checked="" type="radio"/> |
|----------|---|

---

|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

---

|                      |       |
|----------------------|-------|
| Modified File Number | <hr/> |
|----------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (34)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10623012 |
|-------------------|----------------------|

---

|             |   |
|-------------|---|
| File Status | Accepted <input checked="" type="radio"/> |
|-------------|---|

---

|                          |       |
|--------------------------|-------|
| Rejection / Error reason | <hr/> |
|--------------------------|-------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 18 AUG 2014 |
|---------------------------------|-------------|

---

|          |   |
|----------|---|
| Operator | Thierry Bachmann <input checked="" type="radio"/> |
|----------|---|

---

|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

---

|                      |       |
|----------------------|-------|
| Modified File Number | <hr/> |
|----------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (35)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10623013 |
|-------------------|----------------------|

---

|             |   |
|-------------|---|
| File Status | Accepted <input checked="" type="radio"/> |
|-------------|---|

---

|                          |       |
|--------------------------|-------|
| Rejection / Error reason | <hr/> |
|--------------------------|-------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 18 AUG 2014 |
|---------------------------------|-------------|

---

|          |   |
|----------|---|
| Operator | Thierry Bachmann <input checked="" type="radio"/> |
|----------|---|

---

|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

---

|                      |       |
|----------------------|-------|
| Modified File Number | <hr/> |
|----------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (36)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10623014 |
|-------------------|----------------------|

---

|             |   |
|-------------|---|
| File Status | Accepted <input checked="" type="radio"/> |
|-------------|---|

---

|                          |       |
|--------------------------|-------|
| Rejection / Error reason | <hr/> |
|--------------------------|-------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 18 AUG 2014 |
|---------------------------------|-------------|

---

|          |   |
|----------|---|
| Operator | Thierry Bachmann <input checked="" type="radio"/> |
|----------|---|

---

|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

---

|                      |       |
|----------------------|-------|
| Modified File Number | <hr/> |
|----------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (37)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10623015 |
|-------------------|----------------------|

---

|             |   |
|-------------|---|
| File Status | Accepted <input checked="" type="radio"/> |
|-------------|---|

---

|                          |       |
|--------------------------|-------|
| Rejection / Error reason | <hr/> |
|--------------------------|-------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 18 AUG 2014 |
|---------------------------------|-------------|

---

|          |   |
|----------|---|
| Operator | Thierry Bachmann <input checked="" type="radio"/> |
|----------|---|

---

|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

---

|                      |       |
|----------------------|-------|
| Modified File Number | <hr/> |
|----------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (38)**

**Generated On: 20 Jul 2016 11:47:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (39)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10623016 |
|-------------------|----------------------|

---

|             |   |
|-------------|---|
| File Status | Accepted <input checked="" type="radio"/> |
|-------------|---|

---

|                          |       |
|--------------------------|-------|
| Rejection / Error reason | <hr/> |
|--------------------------|-------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 18 AUG 2014 |
|---------------------------------|-------------|

---

|          |   |
|----------|---|
| Operator | Thierry Bachmann <input checked="" type="radio"/> |
|----------|---|

---

|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

---

|                      |       |
|----------------------|-------|
| Modified File Number | <hr/> |
|----------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (41)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0164COHA10623017 |
|-------------------|----------------------|

---

|             |   |
|-------------|---|
| File Status | Accepted <input checked="" type="radio"/> |
|-------------|---|

---

|                          |       |
|--------------------------|-------|
| Rejection / Error reason | <hr/> |
|--------------------------|-------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 18 AUG 2014 |
|---------------------------------|-------------|

---

|          |   |
|----------|---|
| Operator | Thierry Bachmann <input checked="" type="radio"/> |
|----------|---|

---

|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

---

|                      |       |
|----------------------|-------|
| Modified File Number | <hr/> |
|----------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (43)**

**Generated On: 20 Jul 2016 11:47:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (44)**

**Generated On: 20 Jul 2016 11:47:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (45)**

**Generated On: 20 Jul 2016 11:47:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (46)**

**Generated On: 20 Jul 2016 11:47:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (47)**

**Generated On: 20 Jul 2016 11:47:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (48)**

**Generated On: 20 Jul 2016 11:47:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (49)**

**Generated On: 20 Jul 2016 11:47:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (50)**

**Generated On: 20 Jul 2016 11:47:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (51)**

**Generated On: 20 Jul 2016 11:47:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (52)**

**Generated On: 20 Jul 2016 11:47:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (53)**

**Generated On: 20 Jul 2016 11:47:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (54)**

**Generated On: 20 Jul 2016 11:47:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (55)**

**Generated On: 20 Jul 2016 11:47:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (56)**

**Generated On: 20 Jul 2016 11:47:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (57)**

**Generated On: 20 Jul 2016 11:47:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (58)**

**Generated On: 20 Jul 2016 11:47:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (59)**

**Generated On: 20 Jul 2016 11:47:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (60)**

**Generated On: 20 Jul 2016 11:47:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (61)**

**Generated On: 20 Jul 2016 11:47:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Topography files status for THS menthol (62)**

**Generated On: 20 Jul 2016 11:47:42**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (1)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1798 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 01 |
|--------------------------|----|

---

|       |   |
|-------|---|
| Level | 0  |
|-------|---|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1798_01_CDL1.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (2)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1798 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 02 |
|--------------------------|----|

---

|       |   |
|-------|---|
| Level | 0  |
|-------|---|

---

|             |       |
|-------------|-------|
| Observation | <hr/> |
|-------------|-------|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1798_02_XEBH.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (3)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1798 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 03 |
|--------------------------|----|

---

|       |   |
|-------|---|
| Level | 0  |
|-------|---|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1798_03_G9OV.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (4)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1798 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 04 |
|--------------------------|----|

---

|       |                                    |
|-------|------------------------------------|
| Level | 0 <input checked="" type="radio"/> |
|-------|------------------------------------|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1798_04_QRKA.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (5)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1798 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 05 |
|--------------------------|----|

---

|       |                                    |
|-------|------------------------------------|
| Level | 0 <input checked="" type="radio"/> |
|-------|------------------------------------|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1798_05_LDE0.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (6)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1798 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 06 |
|--------------------------|----|

---

|       |                                    |
|-------|------------------------------------|
| Level | 0 <input checked="" type="radio"/> |
|-------|------------------------------------|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1798_06_3RQV.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (7)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1798 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 07 |
|--------------------------|----|

---

|       |                                    |
|-------|------------------------------------|
| Level | 0 <input checked="" type="radio"/> |
|-------|------------------------------------|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1798_07_6MW7.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (8)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1798 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 08 |
|--------------------------|----|

---

|       |   |
|-------|---|
| Level | 0  |
|-------|---|

---

|             |       |
|-------------|-------|
| Observation | <hr/> |
|-------------|-------|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1798_08_PZF8.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (9)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1798 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 09 |
|--------------------------|----|

---

|       |   |
|-------|---|
| Level | 0  |
|-------|---|

---

|             |       |
|-------------|-------|
| Observation | <hr/> |
|-------------|-------|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1798_09_EO5T.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (1)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1802 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 01 |
|--------------------------|----|

---

|       |                                    |
|-------|------------------------------------|
| Level | 0 <input checked="" type="radio"/> |
|-------|------------------------------------|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1802_01_3LNA.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (2)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1802 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 02 |
|--------------------------|----|

---

|       |                                    |
|-------|------------------------------------|
| Level | 0 <input checked="" type="radio"/> |
|-------|------------------------------------|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1802_02_3AN6.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (3)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1802 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 03 |
|--------------------------|----|

---

|       |   |
|-------|---|
| Level | 0  |
|-------|---|

---

|             |       |
|-------------|-------|
| Observation | <hr/> |
|-------------|-------|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1802_03_S5DA.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (4)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1802 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 04 |
|--------------------------|----|

---

|       |   |
|-------|---|
| Level | 0  |
|-------|---|

---

|             |       |
|-------------|-------|
| Observation | <hr/> |
|-------------|-------|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1802_04_I061.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (5)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1802 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 05 |
|--------------------------|----|

---

|       |   |
|-------|---|
| Level | 0  |
|-------|---|

---

|             |       |
|-------------|-------|
| Observation | <hr/> |
|-------------|-------|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1802_05_7XOY.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (6)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1802 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 06 |
|--------------------------|----|

---

|       |   |
|-------|---|
| Level | 0  |
|-------|---|

---

|             |       |
|-------------|-------|
| Observation | <hr/> |
|-------------|-------|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1802_06_EM1Y.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (7)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1802 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 07 |
|--------------------------|----|

---

|       |                                    |
|-------|------------------------------------|
| Level | 0 <input checked="" type="radio"/> |
|-------|------------------------------------|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1802_07_1P28.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (8)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1802 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 08 |
|--------------------------|----|

---

|       |   |
|-------|---|
| Level | 0  |
|-------|---|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1802_08_DFQX.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (9)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1802 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 09 |
|--------------------------|----|

---

|       |   |
|-------|---|
| Level | 0  |
|-------|---|

---

|             |       |
|-------------|-------|
| Observation | <hr/> |
|-------------|-------|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1802_09_H91Q.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (10)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1802 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 10 |
|--------------------------|----|

---

|       |                                    |
|-------|------------------------------------|
| Level | 0 <input checked="" type="radio"/> |
|-------|------------------------------------|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1802_10_4I4G.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (11)**

**Generated On: 20 Jul 2016 11:47:42**


---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1802 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 11 |
|--------------------------|----|

---

|       |   |
|-------|---|
| Level | 0  |
|-------|---|

---

|             |       |
|-------------|-------|
| Observation | <hr/> |
|-------------|-------|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1802_11_55CG.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (1)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1806 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 01 |
|--------------------------|----|

---

|       |   |
|-------|---|
| Level | 0  |
|-------|---|

---

|             |       |
|-------------|-------|
| Observation | <hr/> |
|-------------|-------|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1806_01_PH3B.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (2)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1806 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 02 |
|--------------------------|----|

---

|       |   |
|-------|---|
| Level | 0  |
|-------|---|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1806_02_Q5TW.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (3)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1806 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 03 |
|--------------------------|----|

---

|       |   |
|-------|---|
| Level | 0  |
|-------|---|

---

|             |       |
|-------------|-------|
| Observation | <hr/> |
|-------------|-------|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1806_03_ZNWC.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (4)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1806 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 04 |
|--------------------------|----|

---

|       |   |
|-------|---|
| Level | 0  |
|-------|---|

---

|             |       |
|-------------|-------|
| Observation | <hr/> |
|-------------|-------|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1806_04_DQ70.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (5)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1806 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 05 |
|--------------------------|----|

---

|       |                                    |
|-------|------------------------------------|
| Level | 0 <input checked="" type="radio"/> |
|-------|------------------------------------|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1806_05_5R4J.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (6)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1806 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 06 |
|--------------------------|----|

---

|       |                                    |
|-------|------------------------------------|
| Level | 0 <input checked="" type="radio"/> |
|-------|------------------------------------|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1806_06_241Y.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (7)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1806 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 07 |
|--------------------------|----|

---

|       |                                    |
|-------|------------------------------------|
| Level | 0 <input checked="" type="radio"/> |
|-------|------------------------------------|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1806_07_T9T8.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (8)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1806 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 08 |
|--------------------------|----|

---

|       |                                    |
|-------|------------------------------------|
| Level | 0 <input checked="" type="radio"/> |
|-------|------------------------------------|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1806_08_XLUE.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (9)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1806 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 09 |
|--------------------------|----|

---

|       |   |
|-------|---|
| Level | 0  |
|-------|---|

---

|             |       |
|-------------|-------|
| Observation | <hr/> |
|-------------|-------|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1806_09_Q82M.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (10)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1806 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 10 |
|--------------------------|----|

---

|       |                                    |
|-------|------------------------------------|
| Level | 0 <input checked="" type="radio"/> |
|-------|------------------------------------|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1806_10_48YH.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (1)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1815 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 01 |
|--------------------------|----|

---

|       |                                    |
|-------|------------------------------------|
| Level | 0 <input checked="" type="radio"/> |
|-------|------------------------------------|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1815_01_SXVK.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (2)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1815 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 02 |
|--------------------------|----|

---

|       |   |
|-------|---|
| Level | 0  |
|-------|---|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1815_02_F1PR.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (3)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1815 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 03 |
|--------------------------|----|

---

|       |   |
|-------|---|
| Level | 0  |
|-------|---|

---

|             |       |
|-------------|-------|
| Observation | <hr/> |
|-------------|-------|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1815_03_9YWS.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (4)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1815 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 04 |
|--------------------------|----|

---

|       |                                    |
|-------|------------------------------------|
| Level | 0 <input checked="" type="radio"/> |
|-------|------------------------------------|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1815_04_WH6D.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (5)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1815 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 05 |
|--------------------------|----|

---

|       |                                    |
|-------|------------------------------------|
| Level | 0 <input checked="" type="radio"/> |
|-------|------------------------------------|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1815_05_AQFT.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (6)**

**Generated On: 20 Jul 2016 11:47:42**


---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1815 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 06 |
|--------------------------|----|

---

|       |   |
|-------|---|
| Level | 0  |
|-------|---|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1815_06_AKOA.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (7)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1815 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 07 |
|--------------------------|----|

---

|       |   |
|-------|---|
| Level | 0  |
|-------|---|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1815_07_SM70.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (8)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1815 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 08 |
|--------------------------|----|

---

|       |                          |
|-------|--------------------------|
| Level | NA <input type="radio"/> |
|-------|--------------------------|

---

|             |   |
|-------------|---|
| Observation | No tobacco plug in the vial <input type="radio"/> |
|-------------|---|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1815_08_MF4A.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (9)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1815 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 09 |
|--------------------------|----|

---

|       |                                    |
|-------|------------------------------------|
| Level | 0 <input checked="" type="radio"/> |
|-------|------------------------------------|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1815_09_X8VW.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (10)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1815 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 10 |
|--------------------------|----|

---

|       |   |
|-------|---|
| Level | 0  |
|-------|---|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1815_10_UPVW.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (11)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1815 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 11 |
|--------------------------|----|

---

|       |   |
|-------|---|
| Level | 0  |
|-------|---|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1815_11_TIKL.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (12)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1815 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 12 |
|--------------------------|----|

---

|       |                         |
|-------|-------------------------|
| Level | 0 <input type="radio"/> |
|-------|-------------------------|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1815_12_8JXM.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (1)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1818 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 01 |
|--------------------------|----|

---

|       |   |
|-------|---|
| Level | 0  |
|-------|---|

---

|             |       |
|-------------|-------|
| Observation | <hr/> |
|-------------|-------|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1818_01_25I9.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (2)**

**Generated On: 20 Jul 2016 11:47:42**


---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1818 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 02 |
|--------------------------|----|

---

|       |   |
|-------|---|
| Level | 0  |
|-------|---|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1818_02_DISI.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (3)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1818 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 03 |
|--------------------------|----|

---

|       |                                    |
|-------|------------------------------------|
| Level | 0 <input checked="" type="radio"/> |
|-------|------------------------------------|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1818_03_J9X6.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (4)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1818 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 04 |
|--------------------------|----|

---

|       |                                    |
|-------|------------------------------------|
| Level | 0 <input checked="" type="radio"/> |
|-------|------------------------------------|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1818_04_JPJQ.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (5)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1818 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 05 |
|--------------------------|----|

---

|       |                                    |
|-------|------------------------------------|
| Level | 0 <input checked="" type="radio"/> |
|-------|------------------------------------|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1818_05_HOOL.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (6)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1818 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 06 |
|--------------------------|----|

---

|       |   |
|-------|---|
| Level | 0  |
|-------|---|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1818_06_Q6J1.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (7)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1818 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 07 |
|--------------------------|----|

---

|       |   |
|-------|---|
| Level | 0  |
|-------|---|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1818_07_VNP4.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (8)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1818 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 08 |
|--------------------------|----|

---

|       |   |
|-------|---|
| Level | 0  |
|-------|---|

---

|             |       |
|-------------|-------|
| Observation | <hr/> |
|-------------|-------|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1818_08_109L.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (9)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1818 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 09 |
|--------------------------|----|

---

|       |   |
|-------|---|
| Level | 0  |
|-------|---|

---

|             |       |
|-------------|-------|
| Observation | <hr/> |
|-------------|-------|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1818_09_5ZQC.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (10)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1818 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 10 |
|--------------------------|----|

---

|       |                         |
|-------|-------------------------|
| Level | 0 <input type="radio"/> |
|-------|-------------------------|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1818_10_CZB5.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (11)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1818 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 11 |
|--------------------------|----|

---

|       |   |
|-------|---|
| Level | 0  |
|-------|---|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1818_11_NGVQ.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (12)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1818 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 12 |
|--------------------------|----|

---

|       |   |
|-------|---|
| Level | 0  |
|-------|---|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1818_12_VIR3.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (13)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1818 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 13 |
|--------------------------|----|

---

|       |   |
|-------|---|
| Level | 0  |
|-------|---|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1818_13_PDKZ.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (14)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1818 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 14 |
|--------------------------|----|

---

|       |   |
|-------|---|
| Level | 0  |
|-------|---|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1818_14_U0HW.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (15)**

**Generated On: 20 Jul 2016 11:47:42**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1818 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 15 |
|--------------------------|----|

---

|       |   |
|-------|---|
| Level | 0  |
|-------|---|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1818_15_L61B.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 03 JUN 2014 |
|---------------------------------|-------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Adverse Events**

**Form: Adverse Events Y/N**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:53**

**Generated On: 20 Jul 2016 11:47:42**

---

Was there any Adverse Event for this subject?

Yes ☒

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:53**

**Generated On: 20 Jul 2016 11:47:42**

---

|               |   |
|---------------|---|
| AE Identifier | 1 |
|---------------|---|

---

|               |              |
|---------------|--------------|
| Adverse Event | CONSTIPATION |
|---------------|--------------|

---

|            |             |
|------------|-------------|
| Start Date | 17 JAN 2014 |
|------------|-------------|

DD/MMM/YYYY

---

|          |             |
|----------|-------------|
| End Date | 23 JAN 2014 |
|----------|-------------|

DD/MMM/YYYY

---

|                          |                                     |
|--------------------------|-------------------------------------|
| Ongoing at final contact | No <input checked="" type="radio"/> |
|--------------------------|-------------------------------------|

---

|          |   |
|----------|---|
| Severity | Mild Adverse Event <input checked="" type="radio"/> |
|----------|---|

---

|            |                                     |
|------------|-------------------------------------|
| Serious AE | No <input checked="" type="radio"/> |
|------------|-------------------------------------|

---

Seriousness Criteria

---

|                 |                                     |
|-----------------|-------------------------------------|
| Treatment given | No <input checked="" type="radio"/> |
|-----------------|-------------------------------------|

---

|                               |  |
|-------------------------------|--|
| AE related to Study Procedure | Not Related <input checked="" type="radio"/> |
|-------------------------------|--|

---

|                         |  |
|-------------------------|--|
| Relationship to mCC/THS | Not Related <input checked="" type="radio"/> |
|-------------------------|--|

---

AE expectedness

---

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:53**

**Generated On: 20 Jul 2016 11:47:42**

---

Action taken with study product

None ☒

---

Other action taken

---

---

Outcome

Recovered or Resolved ☒

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:53**

**Generated On: 20 Jul 2016 11:47:42**

---

|               |   |
|---------------|---|
| AE Identifier | 2 |
|---------------|---|

---

|               |                |
|---------------|----------------|
| Adverse Event | FACIAL DRYNESS |
|---------------|----------------|

---

|            |             |
|------------|-------------|
| Start Date | 18 JAN 2014 |
|------------|-------------|

DD/MMM/YYYY

---

|          |             |
|----------|-------------|
| End Date | 21 JAN 2014 |
|----------|-------------|

DD/MMM/YYYY

---

|                          |                                     |
|--------------------------|-------------------------------------|
| Ongoing at final contact | No <input checked="" type="radio"/> |
|--------------------------|-------------------------------------|

---

|          |   |
|----------|---|
| Severity | Mild Adverse Event <input checked="" type="radio"/> |
|----------|---|

---

|            |                                     |
|------------|-------------------------------------|
| Serious AE | No <input checked="" type="radio"/> |
|------------|-------------------------------------|

---

Seriousness Criteria

---

|                 |                                     |
|-----------------|-------------------------------------|
| Treatment given | No <input checked="" type="radio"/> |
|-----------------|-------------------------------------|

---

|                               |  |
|-------------------------------|--|
| AE related to Study Procedure | Not Related <input checked="" type="radio"/> |
|-------------------------------|--|

---

|                         |  |
|-------------------------|--|
| Relationship to mCC/THS | Not Related <input checked="" type="radio"/> |
|-------------------------|--|

---

AE expectedness

---

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:53**

**Generated On: 20 Jul 2016 11:47:42**

---

Action taken with study product

None ☒

---

Other action taken

---

Outcome

Recovered or Resolved ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:53**

**Generated On: 20 Jul 2016 11:47:42**

---

|               |   |
|---------------|---|
| AE Identifier | 3 |
|---------------|---|

---

|               |                |
|---------------|----------------|
| Adverse Event | RIGHT ARM PAIN |
|---------------|----------------|

---

|            |             |
|------------|-------------|
| Start Date | 22 JAN 2014 |
|------------|-------------|

DD/MMM/YYYY

---

End Date

DD/MMM/YYYY

---

|                          |                                      |
|--------------------------|--------------------------------------|
| Ongoing at final contact | Yes <input checked="" type="radio"/> |
|--------------------------|--------------------------------------|

---

|          |   |
|----------|---|
| Severity | Mild Adverse Event <input checked="" type="radio"/> |
|----------|---|

---

|            |                                     |
|------------|-------------------------------------|
| Serious AE | No <input checked="" type="radio"/> |
|------------|-------------------------------------|

---

Seriousness Criteria

---

|                 |                                      |
|-----------------|--------------------------------------|
| Treatment given | Yes <input checked="" type="radio"/> |
|-----------------|--------------------------------------|

---

|                               |  |
|-------------------------------|--|
| AE related to Study Procedure | Related <input checked="" type="radio"/> |
|-------------------------------|--|

---

|                         |  |
|-------------------------|--|
| Relationship to mCC/THS | Not Related <input checked="" type="radio"/> |
|-------------------------|--|

---

AE expectedness

---

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:53**

**Generated On: 20 Jul 2016 11:47:42**

---

Action taken with study product

None ☒

---

Other action taken

---

Outcome

Unknown ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:53**

**Generated On: 20 Jul 2016 11:47:42**

---

|               |   |
|---------------|---|
| AE Identifier | 4 |
|---------------|---|

---

|               |                             |
|---------------|-----------------------------|
| Adverse Event | TINGLING FINGERS RIGHT HAND |
|---------------|-----------------------------|

---

|            |             |
|------------|-------------|
| Start Date | 22 JAN 2014 |
|------------|-------------|

DD/MMM/YYYY

---

End Date

DD/MMM/YYYY

---

|                          |                                      |
|--------------------------|--------------------------------------|
| Ongoing at final contact | Yes <input checked="" type="radio"/> |
|--------------------------|--------------------------------------|

---

|          |   |
|----------|---|
| Severity | Mild Adverse Event <input checked="" type="radio"/> |
|----------|---|

---

|            |                                     |
|------------|-------------------------------------|
| Serious AE | No <input checked="" type="radio"/> |
|------------|-------------------------------------|

---

Seriousness Criteria

---

Treatment given

---

AE related to Study Procedure

---

Relationship to mCC/THS

---

AE expectedness

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:53**

**Generated On: 20 Jul 2016 11:47:42**

---

Action taken with study product

---

Other action taken

---

Outcome

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:53**

**Generated On: 20 Jul 2016 11:47:42**

---

|               |   |
|---------------|---|
| AE Identifier | 5 |
|---------------|---|

---

|               |                 |
|---------------|-----------------|
| Adverse Event | COLD RIGHT HAND |
|---------------|-----------------|

---

|            |             |
|------------|-------------|
| Start Date | 23 JAN 2014 |
|------------|-------------|

DD/MMM/YYYY

---

|          |             |
|----------|-------------|
| End Date | 01 FEB 2014 |
|----------|-------------|

DD/MMM/YYYY

---

|                          |                          |
|--------------------------|--------------------------|
| Ongoing at final contact | No <input type="radio"/> |
|--------------------------|--------------------------|

---

|          |  |
|----------|--|
| Severity | Mild Adverse Event <input type="radio"/> |
|----------|--|

---

|            |                          |
|------------|--------------------------|
| Serious AE | No <input type="radio"/> |
|------------|--------------------------|

---

Seriousness Criteria

---

|                 |                          |
|-----------------|--------------------------|
| Treatment given | No <input type="radio"/> |
|-----------------|--------------------------|

---

|                               |                               |
|-------------------------------|-------------------------------|
| AE related to Study Procedure | Related <input type="radio"/> |
|-------------------------------|-------------------------------|

---

|                         |                                   |
|-------------------------|-----------------------------------|
| Relationship to mCC/THS | Not Related <input type="radio"/> |
|-------------------------|-----------------------------------|

---

AE expectedness

---

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:53**

**Generated On: 20 Jul 2016 11:47:42**

---

Action taken with study product

Product use Interrupted ☒

---

Other action taken

---

Outcome

Recovered or Resolved ☒

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Previous and Concomitant Medication**

**Form: Previous and Concomitant Medication Y/N**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:53**

**Generated On: 20 Jul 2016 11:47:42**

---

Has the subject taken previous or concomitant  
medication?

---

Yes ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Previous and Concomitant Medication**

**Form: Previous and Concomitant Medication (1)**

**Generated On: 20 Jul 2016 11:47:42**

---

|            |           |
|------------|-----------|
| Brand Name | IBUPROFEN |
|------------|-----------|

---

|                           |             |
|---------------------------|-------------|
| Start Date<br>DD/MMM/YYYY | 03 JAN 2014 |
|---------------------------|-------------|

---

|                          |             |
|--------------------------|-------------|
| Stop Date<br>DD/MMM/YYYY | 03 JAN 2014 |
|--------------------------|-------------|

---

|                          |       |
|--------------------------|-------|
| Ongoing at final contact | False |
|--------------------------|-------|

---

|                         |     |
|-------------------------|-----|
| Total Daily dose - Dose | 400 |
|-------------------------|-----|

---

|                         |  |
|-------------------------|--|
| Total Daily dose - Unit | Milligram <input checked="" type="radio"/> |
|-------------------------|--|

---

|       |   |
|-------|---|
| Route | Oral Route of Administration <input checked="" type="radio"/> |
|-------|---|

---

|            |          |
|------------|----------|
| Indication | HEADACHE |
|------------|----------|

---

|                            |   |
|----------------------------|---|
| Concomitant Disease Number | 3 |
|----------------------------|---|

---

|           |       |
|-----------|-------|
| AE Number | <hr/> |
|-----------|-------|

---

|       |       |
|-------|-------|
| Other | <hr/> |
|-------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Previous and Concomitant Medication**

**Form: Previous and Concomitant Medication (2)**

**Generated On: 20 Jul 2016 11:47:42**

---

|            |         |
|------------|---------|
| Brand Name | TYLENOL |
|------------|---------|

---

|                           |             |
|---------------------------|-------------|
| Start Date<br>DD/MMM/YYYY | 08 JAN 2014 |
|---------------------------|-------------|

---

|                          |             |
|--------------------------|-------------|
| Stop Date<br>DD/MMM/YYYY | 08 JAN 2014 |
|--------------------------|-------------|

---

|                          |       |
|--------------------------|-------|
| Ongoing at final contact | False |
|--------------------------|-------|

---

|                         |     |
|-------------------------|-----|
| Total Daily dose - Dose | 500 |
|-------------------------|-----|

---

|                         |  |
|-------------------------|--|
| Total Daily dose - Unit | Milligram <input checked="" type="radio"/> |
|-------------------------|--|

---

|       |   |
|-------|---|
| Route | Oral Route of Administration <input checked="" type="radio"/> |
|-------|---|

---

|            |          |
|------------|----------|
| Indication | HEADACHE |
|------------|----------|

---

|                            |   |
|----------------------------|---|
| Concomitant Disease Number | 3 |
|----------------------------|---|

---

|           |       |
|-----------|-------|
| AE Number | <hr/> |
|-----------|-------|

---

|       |       |
|-------|-------|
| Other | <hr/> |
|-------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Previous and Concomitant Medication**

**Form: Previous and Concomitant Medication (3)**

**Generated On: 20 Jul 2016 11:47:42**

---

|            |         |
|------------|---------|
| Brand Name | TYLENOL |
|------------|---------|

---

|                           |             |
|---------------------------|-------------|
| Start Date<br>DD/MMM/YYYY | 23 JAN 2014 |
|---------------------------|-------------|

---

|                          |  |
|--------------------------|--|
| Stop Date<br>DD/MMM/YYYY |  |
|--------------------------|--|

---

|                          |      |
|--------------------------|------|
| Ongoing at final contact | True |
|--------------------------|------|

---

|                         |      |
|-------------------------|------|
| Total Daily dose - Dose | 1500 |
|-------------------------|------|

---

|                         |  |
|-------------------------|--|
| Total Daily dose - Unit | Milligram <input checked="" type="radio"/> |
|-------------------------|--|

---

|       |   |
|-------|---|
| Route | Oral Route of Administration <input checked="" type="radio"/> |
|-------|---|

---

|            |                |
|------------|----------------|
| Indication | RIGHT ARM PAIN |
|------------|----------------|

---

|                            |  |
|----------------------------|--|
| Concomitant Disease Number |  |
|----------------------------|--|

---

|           |   |
|-----------|---|
| AE Number | 3 |
|-----------|---|

---

|       |  |
|-------|--|
| Other |  |
|-------|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Previous and Concomitant Medication**

**Form: Previous and Concomitant Medication (4)**

**Generated On: 20 Jul 2016 11:47:42**

---

|            |          |
|------------|----------|
| Brand Name | TRAMADOL |
|------------|----------|

---

|                           |             |
|---------------------------|-------------|
| Start Date<br>DD/MMM/YYYY | 27 JAN 2014 |
|---------------------------|-------------|

---

|                          |             |
|--------------------------|-------------|
| Stop Date<br>DD/MMM/YYYY | 06 FEB 2014 |
|--------------------------|-------------|

---

|                          |       |
|--------------------------|-------|
| Ongoing at final contact | False |
|--------------------------|-------|

---

|                         |     |
|-------------------------|-----|
| Total Daily dose - Dose | 120 |
|-------------------------|-----|

---

|                         |  |
|-------------------------|--|
| Total Daily dose - Unit | Milligram <input checked="" type="radio"/> |
|-------------------------|--|

---

|       |   |
|-------|---|
| Route | Oral Route of Administration <input checked="" type="radio"/> |
|-------|---|

---

|            |                |
|------------|----------------|
| Indication | RIGHT ARM PAIN |
|------------|----------------|

---

|                            |       |
|----------------------------|-------|
| Concomitant Disease Number | <hr/> |
|----------------------------|-------|

---

|           |   |
|-----------|---|
| AE Number | 3 |
|-----------|---|

---

|       |       |
|-------|-------|
| Other | <hr/> |
|-------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Previous and Concomitant Medication**

**Form: Previous and Concomitant Medication (5)**

**Generated On: 20 Jul 2016 11:47:42**

---

|            |           |
|------------|-----------|
| Brand Name | IBUPROFEN |
|------------|-----------|

---

|                           |             |
|---------------------------|-------------|
| Start Date<br>DD/MMM/YYYY | 27 JAN 2014 |
|---------------------------|-------------|

---

|                          |             |
|--------------------------|-------------|
| Stop Date<br>DD/MMM/YYYY | 30 JAN 2014 |
|--------------------------|-------------|

---

|                          |       |
|--------------------------|-------|
| Ongoing at final contact | False |
|--------------------------|-------|

---

|                         |      |
|-------------------------|------|
| Total Daily dose - Dose | 3200 |
|-------------------------|------|

---

|                         |  |
|-------------------------|--|
| Total Daily dose - Unit | Milligram <input checked="" type="radio"/> |
|-------------------------|--|

---

|       |   |
|-------|---|
| Route | Oral Route of Administration <input checked="" type="radio"/> |
|-------|---|

---

|            |                |
|------------|----------------|
| Indication | RIGHT ARM PAIN |
|------------|----------------|

---

|                            |       |
|----------------------------|-------|
| Concomitant Disease Number | <hr/> |
|----------------------------|-------|

---

|           |   |
|-----------|---|
| AE Number | 3 |
|-----------|---|

---

|       |       |
|-------|-------|
| Other | <hr/> |
|-------|-------|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Previous and Concomitant Medication**

**Form: Previous and Concomitant Medication (6)**

**Generated On: 20 Jul 2016 11:47:42**

---

|            |             |
|------------|-------------|
| Brand Name | GIABAPENTIN |
|------------|-------------|

---

|                           |             |
|---------------------------|-------------|
| Start Date<br>DD/MMM/YYYY | 07 FEB 2014 |
|---------------------------|-------------|

---

|                          |             |
|--------------------------|-------------|
| Stop Date<br>DD/MMM/YYYY | 20 FEB 2014 |
|--------------------------|-------------|

---

|                          |       |
|--------------------------|-------|
| Ongoing at final contact | False |
|--------------------------|-------|

---

|                         |     |
|-------------------------|-----|
| Total Daily dose - Dose | 300 |
|-------------------------|-----|

---

|                         |  |
|-------------------------|--|
| Total Daily dose - Unit | Milligram <input checked="" type="radio"/> |
|-------------------------|--|

---

|       |   |
|-------|---|
| Route | Oral Route of Administration <input checked="" type="radio"/> |
|-------|---|

---

|            |                |
|------------|----------------|
| Indication | RIGHT ARM PAIN |
|------------|----------------|

---

|                            |       |
|----------------------------|-------|
| Concomitant Disease Number | <hr/> |
|----------------------------|-------|

---

|           |   |
|-----------|---|
| AE Number | 3 |
|-----------|---|

---

|       |       |
|-------|-------|
| Other | <hr/> |
|-------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Previous and Concomitant Medication**

**Form: Previous and Concomitant Medication (7)**

**Generated On: 20 Jul 2016 11:47:42**

---

|            |                               |
|------------|-------------------------------|
| Brand Name | HYDROCODONE/ACETAMINOP<br>HEN |
|------------|-------------------------------|

---

---

|                           |             |
|---------------------------|-------------|
| Start Date<br>DD/MMM/YYYY | 07 FEB 2014 |
|---------------------------|-------------|

---

---

|                          |             |
|--------------------------|-------------|
| Stop Date<br>DD/MMM/YYYY | 16 FEB 2014 |
|--------------------------|-------------|

---

---

|                          |       |
|--------------------------|-------|
| Ongoing at final contact | False |
|--------------------------|-------|

---

---

|                         |   |
|-------------------------|---|
| Total Daily dose - Dose | 1 |
|-------------------------|---|

---

---

|                         |   |
|-------------------------|---|
| Total Daily dose - Unit | Tablet Dosing Unit <input checked="" type="radio"/> |
|-------------------------|---|

---

---

|       |  |
|-------|--|
| Route | Oral Route of<br>Administration <input checked="" type="radio"/> |
|-------|--|

---

---

|            |                |
|------------|----------------|
| Indication | RIGHT ARM PAIN |
|------------|----------------|

---

---

|                            |       |
|----------------------------|-------|
| Concomitant Disease Number | <hr/> |
|----------------------------|-------|

---

---

|           |   |
|-----------|---|
| AE Number | 3 |
|-----------|---|

---

---

|       |       |
|-------|-------|
| Other | <hr/> |
|-------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Previous and Concomitant Medication**

**Form: Previous and Concomitant Medication (8)**

**Generated On: 20 Jul 2016 11:47:42**

---

|            |                    |
|------------|--------------------|
| Brand Name | METHYLPREDNISOLONE |
|------------|--------------------|

---

|                           |             |
|---------------------------|-------------|
| Start Date<br>DD/MMM/YYYY | 07 FEB 2014 |
|---------------------------|-------------|

---

|                          |             |
|--------------------------|-------------|
| Stop Date<br>DD/MMM/YYYY | 07 FEB 2014 |
|--------------------------|-------------|

---

|                          |       |
|--------------------------|-------|
| Ongoing at final contact | False |
|--------------------------|-------|

---

|                         |    |
|-------------------------|----|
| Total Daily dose - Dose | 24 |
|-------------------------|----|

---

|                         |  |
|-------------------------|--|
| Total Daily dose - Unit | Milligram <input checked="" type="radio"/> |
|-------------------------|--|

---

|       |   |
|-------|---|
| Route | Oral Route of Administration <input checked="" type="radio"/> |
|-------|---|

---

|            |                |
|------------|----------------|
| Indication | RIGHT ARM PAIN |
|------------|----------------|

---

|                            |       |
|----------------------------|-------|
| Concomitant Disease Number | <hr/> |
|----------------------------|-------|

---

|           |   |
|-----------|---|
| AE Number | 3 |
|-----------|---|

---

|       |       |
|-------|-------|
| Other | <hr/> |
|-------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Previous and Concomitant Medication**

**Form: Previous and Concomitant Medication (9)**

**Generated On: 20 Jul 2016 11:47:42**

---

|            |                    |
|------------|--------------------|
| Brand Name | METHYLPREDNISOLONE |
|------------|--------------------|

---

|                           |             |
|---------------------------|-------------|
| Start Date<br>DD/MMM/YYYY | 08 FEB 2014 |
|---------------------------|-------------|

---

|                          |             |
|--------------------------|-------------|
| Stop Date<br>DD/MMM/YYYY | 08 FEB 2014 |
|--------------------------|-------------|

---

|                          |       |
|--------------------------|-------|
| Ongoing at final contact | False |
|--------------------------|-------|

---

|                         |    |
|-------------------------|----|
| Total Daily dose - Dose | 20 |
|-------------------------|----|

---

|                         |  |
|-------------------------|--|
| Total Daily dose - Unit | Milligram <input checked="" type="radio"/> |
|-------------------------|--|

---

|       |   |
|-------|---|
| Route | Oral Route of Administration <input checked="" type="radio"/> |
|-------|---|

---

|            |                |
|------------|----------------|
| Indication | RIGHT ARM PAIN |
|------------|----------------|

---

|                            |       |
|----------------------------|-------|
| Concomitant Disease Number | <hr/> |
|----------------------------|-------|

---

|           |   |
|-----------|---|
| AE Number | 3 |
|-----------|---|

---

|       |       |
|-------|-------|
| Other | <hr/> |
|-------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Previous and Concomitant Medication**

**Form: Previous and Concomitant Medication (10)**

**Generated On: 20 Jul 2016 11:47:42**

---

|            |                    |
|------------|--------------------|
| Brand Name | METHYLPREDNISOLONE |
|------------|--------------------|

---

|                           |             |
|---------------------------|-------------|
| Start Date<br>DD/MMM/YYYY | 09 FEB 2014 |
|---------------------------|-------------|

---

|                          |             |
|--------------------------|-------------|
| Stop Date<br>DD/MMM/YYYY | 09 FEB 2014 |
|--------------------------|-------------|

---

|                          |       |
|--------------------------|-------|
| Ongoing at final contact | False |
|--------------------------|-------|

---

|                         |    |
|-------------------------|----|
| Total Daily dose - Dose | 16 |
|-------------------------|----|

---

|                         |  |
|-------------------------|--|
| Total Daily dose - Unit | Milligram <input checked="" type="radio"/> |
|-------------------------|--|

---

|       |   |
|-------|---|
| Route | Oral Route of Administration <input checked="" type="radio"/> |
|-------|---|

---

|            |                |
|------------|----------------|
| Indication | RIGHT ARM PAIN |
|------------|----------------|

---

|                            |       |
|----------------------------|-------|
| Concomitant Disease Number | <hr/> |
|----------------------------|-------|

---

|           |   |
|-----------|---|
| AE Number | 3 |
|-----------|---|

---

|       |       |
|-------|-------|
| Other | <hr/> |
|-------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Previous and Concomitant Medication**

**Form: Previous and Concomitant Medication (11)**

**Generated On: 20 Jul 2016 11:47:42**

---

|            |                    |
|------------|--------------------|
| Brand Name | METHYLPREDNISOLONE |
|------------|--------------------|

---

|                           |             |
|---------------------------|-------------|
| Start Date<br>DD/MMM/YYYY | 10 FEB 2014 |
|---------------------------|-------------|

---

|                          |             |
|--------------------------|-------------|
| Stop Date<br>DD/MMM/YYYY | 10 FEB 2014 |
|--------------------------|-------------|

---

|                          |       |
|--------------------------|-------|
| Ongoing at final contact | False |
|--------------------------|-------|

---

|                         |    |
|-------------------------|----|
| Total Daily dose - Dose | 12 |
|-------------------------|----|

---

|                         |  |
|-------------------------|--|
| Total Daily dose - Unit | Milligram <input checked="" type="radio"/> |
|-------------------------|--|

---

|       |   |
|-------|---|
| Route | Oral Route of Administration <input checked="" type="radio"/> |
|-------|---|

---

|            |                |
|------------|----------------|
| Indication | RIGHT ARM PAIN |
|------------|----------------|

---

|                            |       |
|----------------------------|-------|
| Concomitant Disease Number | <hr/> |
|----------------------------|-------|

---

|           |   |
|-----------|---|
| AE Number | 3 |
|-----------|---|

---

|       |       |
|-------|-------|
| Other | <hr/> |
|-------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Previous and Concomitant Medication**

**Form: Previous and Concomitant Medication (12)**

**Generated On: 20 Jul 2016 11:47:42**

---

|            |                    |
|------------|--------------------|
| Brand Name | METHYLPREDNISOLONE |
|------------|--------------------|

---

|                           |             |
|---------------------------|-------------|
| Start Date<br>DD/MMM/YYYY | 11 FEB 2014 |
|---------------------------|-------------|

---

|                          |             |
|--------------------------|-------------|
| Stop Date<br>DD/MMM/YYYY | 11 FEB 2014 |
|--------------------------|-------------|

---

|                          |       |
|--------------------------|-------|
| Ongoing at final contact | False |
|--------------------------|-------|

---

|                         |   |
|-------------------------|---|
| Total Daily dose - Dose | 8 |
|-------------------------|---|

---

|                         |  |
|-------------------------|--|
| Total Daily dose - Unit | Milligram <input checked="" type="radio"/> |
|-------------------------|--|

---

|       |   |
|-------|---|
| Route | Oral Route of Administration <input checked="" type="radio"/> |
|-------|---|

---

|            |                |
|------------|----------------|
| Indication | RIGHT ARM PAIN |
|------------|----------------|

---

|                            |       |
|----------------------------|-------|
| Concomitant Disease Number | <hr/> |
|----------------------------|-------|

---

|           |   |
|-----------|---|
| AE Number | 3 |
|-----------|---|

---

|       |       |
|-------|-------|
| Other | <hr/> |
|-------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Previous and Concomitant Medication**

**Form: Previous and Concomitant Medication (13)**

**Generated On: 20 Jul 2016 11:47:42**

---

|            |                    |
|------------|--------------------|
| Brand Name | METHYLPREDNISOLONE |
|------------|--------------------|

---

|                           |             |
|---------------------------|-------------|
| Start Date<br>DD/MMM/YYYY | 12 FEB 2014 |
|---------------------------|-------------|

---

|                          |             |
|--------------------------|-------------|
| Stop Date<br>DD/MMM/YYYY | 12 FEB 2014 |
|--------------------------|-------------|

---

|                          |       |
|--------------------------|-------|
| Ongoing at final contact | False |
|--------------------------|-------|

---

|                         |   |
|-------------------------|---|
| Total Daily dose - Dose | 4 |
|-------------------------|---|

---

|                         |  |
|-------------------------|--|
| Total Daily dose - Unit | Milligram <input checked="" type="radio"/> |
|-------------------------|--|

---

|       |   |
|-------|---|
| Route | Oral Route of Administration <input checked="" type="radio"/> |
|-------|---|

---

|            |                |
|------------|----------------|
| Indication | RIGHT ARM PAIN |
|------------|----------------|

---

|                            |       |
|----------------------------|-------|
| Concomitant Disease Number | <hr/> |
|----------------------------|-------|

---

|           |   |
|-----------|---|
| AE Number | 3 |
|-----------|---|

---

|       |       |
|-------|-------|
| Other | <hr/> |
|-------|-------|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Previous and Concomitant Medication**

**Form: Previous and Concomitant Medication (14)**

**Generated On: 20 Jul 2016 11:47:42**

---

|            |             |
|------------|-------------|
| Brand Name | GIABAPENTIN |
|------------|-------------|

---

|                           |             |
|---------------------------|-------------|
| Start Date<br>DD/MMM/YYYY | 24 FEB 2014 |
|---------------------------|-------------|

---

|                          |  |
|--------------------------|--|
| Stop Date<br>DD/MMM/YYYY |  |
|--------------------------|--|

---

|                          |      |
|--------------------------|------|
| Ongoing at final contact | True |
|--------------------------|------|

---

|                         |     |
|-------------------------|-----|
| Total Daily dose - Dose | 900 |
|-------------------------|-----|

---

|                         |  |
|-------------------------|--|
| Total Daily dose - Unit | Milligram <input checked="" type="radio"/> |
|-------------------------|--|

---

|       |   |
|-------|---|
| Route | Oral Route of Administration <input checked="" type="radio"/> |
|-------|---|

---

|            |                |
|------------|----------------|
| Indication | RIGHT ARM PAIN |
|------------|----------------|

---

|                            |  |
|----------------------------|--|
| Concomitant Disease Number |  |
|----------------------------|--|

---

|           |   |
|-----------|---|
| AE Number | 3 |
|-----------|---|

---

|       |  |
|-------|--|
| Other |  |
|-------|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Previous and Concomitant Medication**

**Form: Previous and Concomitant Medication (15)**

**Generated On: 20 Jul 2016 11:47:42**

---

Brand Name

GIABAPENTIN

---

Start Date  
DD/MMM/YYYY

21 FEB 2014

---

Stop Date  
DD/MMM/YYYY

---

Ongoing at final contact

True

---

Total Daily dose - Dose

10

---

Total Daily dose - Unit

Milligram ☒

---

Route

Oral Route of  
Administration ☒

---

Indication

RIGHT ARM PAIN

---

Concomitant Disease Number

---

AE Number

3

---

Other

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Previous and Concomitant Medication**

**Form: Previous and Concomitant Medication (16)**

**Generated On: 20 Jul 2016 11:47:42**

---

|            |               |
|------------|---------------|
| Brand Name | AMITRIPTYLINE |
|------------|---------------|

---

|                           |             |
|---------------------------|-------------|
| Start Date<br>DD/MMM/YYYY | 21 FEB 2014 |
|---------------------------|-------------|

---

|                          |  |
|--------------------------|--|
| Stop Date<br>DD/MMM/YYYY |  |
|--------------------------|--|

---

|                          |      |
|--------------------------|------|
| Ongoing at final contact | True |
|--------------------------|------|

---

|                         |    |
|-------------------------|----|
| Total Daily dose - Dose | 10 |
|-------------------------|----|

---

|                         |  |
|-------------------------|--|
| Total Daily dose - Unit | Milligram <input checked="" type="radio"/> |
|-------------------------|--|

---

|       |   |
|-------|---|
| Route | Oral Route of Administration <input checked="" type="radio"/> |
|-------|---|

---

|            |                |
|------------|----------------|
| Indication | RIGHT ARM PAIN |
|------------|----------------|

---

|                            |  |
|----------------------------|--|
| Concomitant Disease Number |  |
|----------------------------|--|

---

|           |   |
|-----------|---|
| AE Number | 3 |
|-----------|---|

---

|       |  |
|-------|--|
| Other |  |
|-------|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Device Events**

**Form: Device report - THS 2.2 menthol Cigarette Holder**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:56**

**Generated On: 20 Jul 2016 11:47:42**

---

Were there any events with the device?

Yes ☒

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Device Events**

**Form: Device report - THS 2.2 menthol Cigarette Holder (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:56**

**Generated On: 20 Jul 2016 11:47:42**

---

Were there any events with the device? Yes ☒

---

Event Log Number 1

---

Date of Device Event 20 JAN 2014  
DD/MMM/YYYY

---

Time of Device Event 07:49  
hour:min 24-hour clock

---

Event Relates to Device Type: THS 2.2 CIGARETTE HOLDER

---

Unique Device Identifier Serial Number 1245457

---

Event Description Other ☒

---

Other Describe TOP OF HOLDER STUCK IN CHARGER

---

Severity of Event Major (cannot be resolved. Device needs to be exchanged) ☒

---

Adverse Event Relationship Is not related to AE ☒

---

If Related to AE, AE Number \_\_\_\_\_

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Device Events**

**Form: Device report - THS 2.2 menthol Cigarette Holder (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:56**

**Generated On: 20 Jul 2016 11:47:42**

---

Solution Proposed:

Device Replaced ☒

---

If the device was replaced, New Device Serial Number:

1245404

---

Date of Device Event Closure  
DD/MMM/YYYY

20 JAN 2014

---

Time of Device Event Closure  
hour:min 24-hour clock

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Device Events**

**Form: Device report - THS 2.2 menthol Cigarette Holder (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:56**

**Generated On: 20 Jul 2016 11:47:42**

---

Were there any events with the device? Yes ☒

---

Event Log Number 2

---

Date of Device Event 20 JAN 2014  
DD/MMM/YYYY

---

Time of  
Device Event  
hour:min 24-hour clock

---

Event Relates to Device Type: THS 2.2 CIGARETTE HOLDER

---

Unique Device Identifier Serial Number 1308301

---

Event Description Other ☒

---

Other Describe UNKNOWN DEVICE TAKEN  
OUT OF SERVICE PRIOR TO  
LOGS IMPLEMENTATION

---

Severity of Event Major (cannot be resolved.  
Device needs to be  
exchanged) ☒

---

Adverse Event Relationship Is not related to AE ☒

---

If Related to AE, AE Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Device Events**

**Form: Device report - THS 2.2 menthol Cigarette Holder (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:56**

**Generated On: 20 Jul 2016 11:47:42**

---

Solution Proposed:

Device Replaced ☒

---

If the device was replaced, New Device Serial Number:

1249262

---

Date of Device Event Closure  
DD/MMM/YYYY

---

Time of Device Event Closure  
hour:min 24-hour clock



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Device Events**

**Form: Device report - THS 2.2 menthol Charging Unit**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:57**

**Generated On: 20 Jul 2016 11:47:42**

---

Were there any events with the device?

Yes ☒

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Folder: Device Events**

**Form: Device report - THS 2.2 menthol Charging Unit (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:57**

**Generated On: 20 Jul 2016 11:47:42**

---

Were there any events with the device? Yes ☒

---

Event Log Number 1

---

Date of Device Event 20 JAN 2014  
DD/MMM/YYYY

---

Time of  
Device Event  
hour:min 24-hour clock

---

Event Relates to THS 2.2 CHARGING UNIT  
Device Type:

---

Unique Device Identifier Serial Number 1318369

---

Event Description Other ☒

---

Other Describe UNKNOWN DEVICE TAKEN  
OUT OF SERVICE PRIOR TO  
LOGS IMPLEMENTATION

---

Severity of Event Major (cannot be resolved. ☒  
Device needs to be  
exchanged)

---

Adverse Event Is not related to AE ☒  
Relationship

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Device Events**

**Form: Device report - THS 2.2 menthol Charging Unit (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:57**

**Generated On: 20 Jul 2016 11:47:42**

---

Solution Proposed:

Device Replaced ☒

---

If the device was replaced, New Device Serial Number:

1318319

---

Date of Device Event Closure  
DD/MMM/YYYY

26 FEB 2014

---

Time of Device Event Closure  
hour:min 24-hour clock

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Device Inventory**

**Form: Device Inventory - THS 2.2 menthol Cigarette Holder (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:58**

**Generated On: 20 Jul 2016 11:47:42**

---

|                  |   |
|------------------|---|
| Device Inventory | 1 |
| Log Number       |   |

---

|                             |             |
|-----------------------------|-------------|
| Date of Device Distribution | 17 JAN 2014 |
| DD/MMM/YYYY                 |             |

---

|                        |       |
|------------------------|-------|
| Time of                | 07:49 |
| Device Distribution    |       |
| hour:min 24-hour clock |       |

---

|             |                          |
|-------------|--------------------------|
| Device Type | THS 2.2 CIGARETTE HOLDER |
|-------------|--------------------------|

---

|                      |         |
|----------------------|---------|
| Device Serial Number | 1245457 |
|----------------------|---------|

---

|                           |             |
|---------------------------|-------------|
| Date of Device Collection | 20 JAN 2014 |
| DD/MMM/YYYY               |             |

---

|                        |       |
|------------------------|-------|
| Time of                | 09:28 |
| Device Collection      |       |
| hour:min 24-hour clock |       |

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Device Inventory**

**Form: Device Inventory - THS 2.2 menthol Cigarette Holder (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:58**

**Generated On: 20 Jul 2016 11:47:42**

---

|                  |   |
|------------------|---|
| Device Inventory | 2 |
| Log Number       |   |

---

|                             |             |
|-----------------------------|-------------|
| Date of Device Distribution | 17 JAN 2014 |
| DD/MMM/YYYY                 |             |

---

|                        |       |
|------------------------|-------|
| Time of                | 07:49 |
| Device Distribution    |       |
| hour:min 24-hour clock |       |

---

|             |                          |
|-------------|--------------------------|
| Device Type | THS 2.2 CIGARETTE HOLDER |
|-------------|--------------------------|

---

|                      |         |
|----------------------|---------|
| Device Serial Number | 1308301 |
|----------------------|---------|

---

|                           |             |
|---------------------------|-------------|
| Date of Device Collection | 20 JAN 2014 |
| DD/MMM/YYYY               |             |

---

|                        |       |
|------------------------|-------|
| Time of                | 09:28 |
| Device Collection      |       |
| hour:min 24-hour clock |       |

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Device Inventory**

**Form: Device Inventory - THS 2.2 menthol Cigarette Holder (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:58**

**Generated On: 20 Jul 2016 11:47:42**

---

|                  |   |
|------------------|---|
| Device Inventory | 3 |
| Log Number       |   |

---

|                             |             |
|-----------------------------|-------------|
| Date of Device Distribution | 20 JAN 2014 |
| DD/MMM/YYYY                 |             |

---

|                        |       |
|------------------------|-------|
| Time of                | 11:21 |
| Device Distribution    |       |
| hour:min 24-hour clock |       |

---

|             |                          |
|-------------|--------------------------|
| Device Type | THS 2.2 CIGARETTE HOLDER |
|-------------|--------------------------|

---

|                      |         |
|----------------------|---------|
| Device Serial Number | 1245404 |
|----------------------|---------|

---

|                           |             |
|---------------------------|-------------|
| Date of Device Collection | 22 JAN 2014 |
| DD/MMM/YYYY               |             |

---

|                        |       |
|------------------------|-------|
| Time of                | 12:51 |
| Device Collection      |       |
| hour:min 24-hour clock |       |

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Device Inventory**

**Form: Device Inventory - THS 2.2 menthol Cigarette Holder (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:58**

**Generated On: 20 Jul 2016 11:47:42**

---

|                  |   |
|------------------|---|
| Device Inventory | 4 |
| Log Number       |   |

---

|                             |             |
|-----------------------------|-------------|
| Date of Device Distribution | 20 JAN 2014 |
| DD/MMM/YYYY                 |             |

---

|                        |       |
|------------------------|-------|
| Time of                | 11:21 |
| Device Distribution    |       |
| hour:min 24-hour clock |       |

---

|             |                          |
|-------------|--------------------------|
| Device Type | THS 2.2 CIGARETTE HOLDER |
|-------------|--------------------------|

---

|                      |         |
|----------------------|---------|
| Device Serial Number | 1249262 |
|----------------------|---------|

---

|                           |             |
|---------------------------|-------------|
| Date of Device Collection | 22 JAN 2014 |
| DD/MMM/YYYY               |             |

---

|                        |       |
|------------------------|-------|
| Time of                | 12:51 |
| Device Collection      |       |
| hour:min 24-hour clock |       |

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Device Inventory**

**Form: Device Inventory - THS 2.2 menthol Charging Unit (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:59**

**Generated On: 20 Jul 2016 11:47:42**

---

|                  |   |
|------------------|---|
| Device Inventory | 1 |
| Log Number       |   |

---

|                             |             |
|-----------------------------|-------------|
| Date of Device Distribution | 17 JAN 2014 |
| DD/MMM/YYYY                 |             |

---

|                        |       |
|------------------------|-------|
| Time of                | 07:49 |
| Device Distribution    |       |
| hour:min 24-hour clock |       |

---

|             |                       |
|-------------|-----------------------|
| Device Type | THS 2.2 CHARGING UNIT |
|-------------|-----------------------|

---

|                      |         |
|----------------------|---------|
| Device Serial Number | 1318369 |
|----------------------|---------|

---

|                           |             |
|---------------------------|-------------|
| Date of Device Collection | 20 JAN 2014 |
| DD/MMM/YYYY               |             |

---

|                        |       |
|------------------------|-------|
| Time of                | 09:28 |
| Device Collection      |       |
| hour:min 24-hour clock |       |

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Folder: Device Inventory**

**Form: Device Inventory - THS 2.2 menthol Charging Unit (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:47:59**

**Generated On: 20 Jul 2016 11:47:42**

---

|                  |   |
|------------------|---|
| Device Inventory | 2 |
| Log Number       |   |

---

|                             |             |
|-----------------------------|-------------|
| Date of Device Distribution | 20 JAN 2014 |
| DD/MMM/YYYY                 |             |

---

|                        |       |
|------------------------|-------|
| Time of                | 11:21 |
| Device Distribution    |       |
| hour:min 24-hour clock |       |

---

|             |                       |
|-------------|-----------------------|
| Device Type | THS 2.2 CHARGING UNIT |
|-------------|-----------------------|

---

|                      |         |
|----------------------|---------|
| Device Serial Number | 1318319 |
|----------------------|---------|

---

|                           |             |
|---------------------------|-------------|
| Date of Device Collection | 22 JAN 2014 |
| DD/MMM/YYYY               |             |

---

|                        |       |
|------------------------|-------|
| Time of                | 12:51 |
| Device Collection      |       |
| hour:min 24-hour clock |       |

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

|   |   |
|---|---|
| Date of Birth   | (b) (6)   |
| Date of completion<br>DD/MMM/YYYY                       | 2014 JAN 22                                     |
| Time of completion<br>hh:mm                             | 19:50   |
| Date the questionnaire was completed for<br>DD/MMM/YYYY | 2014 JAN 22                                     |
| Assessment Status                                       | Completed <input checked="" type="radio"/>      |
| What tobacco/nicotine product did you use today?        | THS 2.2 <input checked="" type="radio"/>        |
| How many THS 2.2 tobacco sticks did you use today?      | 8   |
| How many CC/ roll-your-own did you smoke today?         | -9  |
| What NRT product did you used today?                    | Not Applicable <input checked="" type="radio"/> |
| How many times did you use an inhaler today?            | -9  |
| How many times did you use a nasal spray today?         | -9  |
| How many gums did you use today?                        | -9  |
| How many lozenges did you use today?                    | -9  |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (1)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                     |    |
|-------------------------------------|----|
| How many patches did you use today? | -9 |
|-------------------------------------|----|

---

|  |    |
|--|----|
| How many times did you use other NRT products today not listed previously? | -9 |
|--|----|

---

|  |   |
|--|---|
| What other tobacco product did you used today? | Not Applicable <input checked="" type="radio"/> |
|--|---|

---

|  |    |
|--|----|
| How many times did you use chewable/smokeless tobacco today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many cigars/cigarillos did you smoke today? | -9 |
|---|----|

---

|  |    |
|--|----|
| How many times did you smoke a pipe today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many times did you use a tobacco product today not listed previously? | -9 |
|---|----|

---

|   |    |
|---|----|
| How many times did you use an electronic cigarette today? | -9 |
|---|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

|   |   |
|---|---|
| Date of Birth   | (b) (6)   |
| Date of completion<br>DD/MMM/YYYY                       | 2014 JAN 23                                     |
| Time of completion<br>hh:mm                             | 18:32   |
| Date the questionnaire was completed for<br>DD/MMM/YYYY | 2014 JAN 23                                     |
| Assessment Status                                       | Completed <input checked="" type="radio"/>      |
| What tobacco/nicotine product did you use today?        | THS 2.2 <input checked="" type="radio"/>        |
| How many THS 2.2 tobacco sticks did you use today?      | 11  |
| How many CC/ roll-your-own did you smoke today?         | -9  |
| What NRT product did you used today?                    | Not Applicable <input checked="" type="radio"/> |
| How many times did you use an inhaler today?            | -9  |
| How many times did you use a nasal spray today?         | -9  |
| How many gums did you use today?                        | -9  |
| How many lozenges did you use today?                    | -9  |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (2)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                     |    |
|-------------------------------------|----|
| How many patches did you use today? | -9 |
|-------------------------------------|----|

---

|  |    |
|--|----|
| How many times did you use other NRT products today not listed previously? | -9 |
|--|----|

---

|  |   |
|--|---|
| What other tobacco product did you used today? | Not Applicable <input checked="" type="radio"/> |
|--|---|

---

|  |    |
|--|----|
| How many times did you use chewable/smokeless tobacco today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many cigars/cigarillos did you smoke today? | -9 |
|---|----|

---

|  |    |
|--|----|
| How many times did you smoke a pipe today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many times did you use a tobacco product today not listed previously? | -9 |
|---|----|

---

|   |    |
|---|----|
| How many times did you use an electronic cigarette today? | -9 |
|---|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

---

Date of Birth

(b) (6)

---

Date of completion  
DD/MMM/YYYY

2014 JAN 24

---

Time of completion  
hh:mm

18:54

---

Date the questionnaire was completed for  
DD/MMM/YYYY

2014 JAN 24

---

Assessment Status

Completed ☒

---

What tobacco/nicotine product did you use today?

THS 2.2 ☒

---

How many THS 2.2 tobacco sticks did you use today?

14

---

How many CC/ roll-your-own did you smoke today?

-9

---

What NRT product did you used today?

Not Applicable ☒

---

How many times did you use an inhaler today?

-9

---

How many times did you use a nasal spray today?

-9

---

How many gums did you use today?

-9

---

How many lozenges did you use today?

-9

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (3)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                     |    |
|-------------------------------------|----|
| How many patches did you use today? | -9 |
|-------------------------------------|----|

---

|  |    |
|--|----|
| How many times did you use other NRT products today not listed previously? | -9 |
|--|----|

---

|  |   |
|--|---|
| What other tobacco product did you used today? | Not Applicable <input checked="" type="radio"/> |
|--|---|

---

|  |    |
|--|----|
| How many times did you use chewable/smokeless tobacco today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many cigars/cigarillos did you smoke today? | -9 |
|---|----|

---

|  |    |
|--|----|
| How many times did you smoke a pipe today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many times did you use a tobacco product today not listed previously? | -9 |
|---|----|

---

|   |    |
|---|----|
| How many times did you use an electronic cigarette today? | -9 |
|---|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

|   |   |
|---|---|
| Date of Birth   | (b) (6)   |
| Date of completion<br>DD/MMM/YYYY                       | 2014 JAN 25                                     |
| Time of completion<br>hh:mm                             | 18:57   |
| Date the questionnaire was completed for<br>DD/MMM/YYYY | 2014 JAN 25                                     |
| Assessment Status                                       | Completed <input checked="" type="radio"/>      |
| What tobacco/nicotine product did you use today?        | THS 2.2 and CC <input checked="" type="radio"/> |
| How many THS 2.2 tobacco sticks did you use today?      | 8   |
| How many CC/ roll-your-own did you smoke today?         | 2   |
| What NRT product did you used today?                    | Not Applicable <input checked="" type="radio"/> |
| How many times did you use an inhaler today?            | -9  |
| How many times did you use a nasal spray today?         | -9  |
| How many gums did you use today?                        | -9  |
| How many lozenges did you use today?                    | -9  |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (4)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                     |    |
|-------------------------------------|----|
| How many patches did you use today? | -9 |
|-------------------------------------|----|

---

|  |    |
|--|----|
| How many times did you use other NRT products today not listed previously? | -9 |
|--|----|

---

|  |   |
|--|---|
| What other tobacco product did you used today? | Not Applicable <input checked="" type="radio"/> |
|--|---|

---

|  |    |
|--|----|
| How many times did you use chewable/smokeless tobacco today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many cigars/cigarillos did you smoke today? | -9 |
|---|----|

---

|  |    |
|--|----|
| How many times did you smoke a pipe today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many times did you use a tobacco product today not listed previously? | -9 |
|---|----|

---

|   |    |
|---|----|
| How many times did you use an electronic cigarette today? | -9 |
|---|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Form: Product use diary (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

|   |   |
|---|---|
| Date of Birth   | (b) (6)   |
| Date of completion<br>DD/MMM/YYYY                       | 2014 JAN 26                                     |
| Time of completion<br>hh:mm                             | 18:35   |
| Date the questionnaire was completed for<br>DD/MMM/YYYY | 2014 JAN 26                                     |
| Assessment Status                                       | Completed <input checked="" type="radio"/>      |
| What tobacco/nicotine product did you use today?        | THS 2.2 <input checked="" type="radio"/>        |
| How many THS 2.2 tobacco sticks did you use today?      | 9   |
| How many CC/ roll-your-own did you smoke today?         | -9  |
| What NRT product did you used today?                    | Not Applicable <input checked="" type="radio"/> |
| How many times did you use an inhaler today?            | -9  |
| How many times did you use a nasal spray today?         | -9  |
| How many gums did you use today?                        | -9  |
| How many lozenges did you use today?                    | -9  |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (5)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                     |    |
|-------------------------------------|----|
| How many patches did you use today? | -9 |
|-------------------------------------|----|

---

|  |    |
|--|----|
| How many times did you use other NRT products today not listed previously? | -9 |
|--|----|

---

|  |   |
|--|---|
| What other tobacco product did you used today? | Not Applicable <input checked="" type="radio"/> |
|--|---|

---

|  |    |
|--|----|
| How many times did you use chewable/smokeless tobacco today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many cigars/cigarillos did you smoke today? | -9 |
|---|----|

---

|  |    |
|--|----|
| How many times did you smoke a pipe today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many times did you use a tobacco product today not listed previously? | -9 |
|---|----|

---

|   |    |
|---|----|
| How many times did you use an electronic cigarette today? | -9 |
|---|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Form: Product use diary (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

|   |   |
|---|---|
| Date of Birth   | (b) (6)   |
| Date of completion<br>DD/MMM/YYYY                       | 2014 JAN 27                                     |
| Time of completion<br>hh:mm                             | 18:46   |
| Date the questionnaire was completed for<br>DD/MMM/YYYY | 2014 JAN 27                                     |
| Assessment Status                                       | Completed <input checked="" type="radio"/>      |
| What tobacco/nicotine product did you use today?        | THS 2.2 <input checked="" type="radio"/>        |
| How many THS 2.2 tobacco sticks did you use today?      | 13  |
| How many CC/ roll-your-own did you smoke today?         | -9  |
| What NRT product did you used today?                    | Not Applicable <input checked="" type="radio"/> |
| How many times did you use an inhaler today?            | -9  |
| How many times did you use a nasal spray today?         | -9  |
| How many gums did you use today?                        | -9  |
| How many lozenges did you use today?                    | -9  |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (6)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                     |    |
|-------------------------------------|----|
| How many patches did you use today? | -9 |
|-------------------------------------|----|

---

|  |    |
|--|----|
| How many times did you use other NRT products today not listed previously? | -9 |
|--|----|

---

|  |   |
|--|---|
| What other tobacco product did you used today? | Not Applicable <input checked="" type="radio"/> |
|--|---|

---

|  |    |
|--|----|
| How many times did you use chewable/smokeless tobacco today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many cigars/cigarillos did you smoke today? | -9 |
|---|----|

---

|  |    |
|--|----|
| How many times did you smoke a pipe today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many times did you use a tobacco product today not listed previously? | -9 |
|---|----|

---

|   |    |
|---|----|
| How many times did you use an electronic cigarette today? | -9 |
|---|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Form: Product use diary (7)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

---

Date of Birth

(b) (6)

---

Date of completion  
DD/MMM/YYYY

2014 JAN 28

---

Time of completion  
hh:mm

18:24

---

Date the questionnaire was completed for  
DD/MMM/YYYY

2014 JAN 28

---

Assessment Status

Completed ☒

---

What tobacco/nicotine product did you use today?

THS 2.2 ☒

---

How many THS 2.2 tobacco sticks did you use today?

7

---

How many CC/ roll-your-own did you smoke today?

-9

---

What NRT product did you used today?

Not Applicable ☒

---

How many times did you use an inhaler today?

-9

---

How many times did you use a nasal spray today?

-9

---

How many gums did you use today?

-9

---

How many lozenges did you use today?

-9

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (7)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                     |    |
|-------------------------------------|----|
| How many patches did you use today? | -9 |
|-------------------------------------|----|

---

|  |    |
|--|----|
| How many times did you use other NRT products today not listed previously? | -9 |
|--|----|

---

|  |   |
|--|---|
| What other tobacco product did you used today? | Not Applicable <input checked="" type="radio"/> |
|--|---|

---

|  |    |
|--|----|
| How many times did you use chewable/smokeless tobacco today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many cigars/cigarillos did you smoke today? | -9 |
|---|----|

---

|  |    |
|--|----|
| How many times did you smoke a pipe today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many times did you use a tobacco product today not listed previously? | -9 |
|---|----|

---

|   |    |
|---|----|
| How many times did you use an electronic cigarette today? | -9 |
|---|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (8)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

|   |   |
|---|---|
| Date of Birth   | (b) (6)   |
| Date of completion<br>DD/MMM/YYYY                       | 2014 JAN 29                                     |
| Time of completion<br>hh:mm                             | 19:55   |
| Date the questionnaire was completed for<br>DD/MMM/YYYY | 2014 JAN 29                                     |
| Assessment Status                                       | Completed <input checked="" type="radio"/>      |
| What tobacco/nicotine product did you use today?        | THS 2.2 and CC <input checked="" type="radio"/> |
| How many THS 2.2 tobacco sticks did you use today?      | 4   |
| How many CC/ roll-your-own did you smoke today?         | 4   |
| What NRT product did you used today?                    | Not Applicable <input checked="" type="radio"/> |
| How many times did you use an inhaler today?            | -9  |
| How many times did you use a nasal spray today?         | -9  |
| How many gums did you use today?                        | -9  |
| How many lozenges did you use today?                    | -9  |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (8)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                     |    |
|-------------------------------------|----|
| How many patches did you use today? | -9 |
|-------------------------------------|----|

---

|  |    |
|--|----|
| How many times did you use other NRT products today not listed previously? | -9 |
|--|----|

---

|  |   |
|--|---|
| What other tobacco product did you used today? | Not Applicable <input checked="" type="radio"/> |
|--|---|

---

|  |    |
|--|----|
| How many times did you use chewable/smokeless tobacco today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many cigars/cigarillos did you smoke today? | -9 |
|---|----|

---

|  |    |
|--|----|
| How many times did you smoke a pipe today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many times did you use a tobacco product today not listed previously? | -9 |
|---|----|

---

|   |    |
|---|----|
| How many times did you use an electronic cigarette today? | -9 |
|---|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (9)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

---

Date of Birth

(b) (6)

---

Date of completion  
DD/MMM/YYYY

2014 JAN 30

---

Time of completion  
hh:mm

18:23

---

Date the questionnaire was completed for  
DD/MMM/YYYY

2014 JAN 30

---

Assessment Status

Completed ☒

---

What tobacco/nicotine product did you use today?

THS 2.2 and CC ☒

---

How many THS 2.2 tobacco sticks did you use today?

9

---

How many CC/ roll-your-own did you smoke today?

3

---

What NRT product did you used today?

Not Applicable ☒

---

How many times did you use an inhaler today?

-9

---

How many times did you use a nasal spray today?

-9

---

How many gums did you use today?

-9

---

How many lozenges did you use today?

-9

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (9)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                     |    |
|-------------------------------------|----|
| How many patches did you use today? | -9 |
|-------------------------------------|----|

---

|  |    |
|--|----|
| How many times did you use other NRT products today not listed previously? | -9 |
|--|----|

---

|  |   |
|--|---|
| What other tobacco product did you used today? | Not Applicable <input checked="" type="radio"/> |
|--|---|

---

|  |    |
|--|----|
| How many times did you use chewable/smokeless tobacco today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many cigars/cigarillos did you smoke today? | -9 |
|---|----|

---

|  |    |
|--|----|
| How many times did you smoke a pipe today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many times did you use a tobacco product today not listed previously? | -9 |
|---|----|

---

|   |    |
|---|----|
| How many times did you use an electronic cigarette today? | -9 |
|---|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (10)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

|   |   |
|---|---|
| Date of Birth   | (b) (6)   |
| Date of completion<br>DD/MMM/YYYY                       | 2014 JAN 31                                     |
| Time of completion<br>hh:mm                             | 18:54   |
| Date the questionnaire was completed for<br>DD/MMM/YYYY | 2014 JAN 31                                     |
| Assessment Status                                       | Completed <input checked="" type="radio"/>      |
| What tobacco/nicotine product did you use today?        | THS 2.2 and CC <input checked="" type="radio"/> |
| How many THS 2.2 tobacco sticks did you use today?      | 9   |
| How many CC/ roll-your-own did you smoke today?         | 3   |
| What NRT product did you used today?                    | Not Applicable <input checked="" type="radio"/> |
| How many times did you use an inhaler today?            | -9  |
| How many times did you use a nasal spray today?         | -9  |
| How many gums did you use today?                        | -9  |
| How many lozenges did you use today?                    | -9  |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (10)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                     |    |
|-------------------------------------|----|
| How many patches did you use today? | -9 |
|-------------------------------------|----|

---

|  |    |
|--|----|
| How many times did you use other NRT products today not listed previously? | -9 |
|--|----|

---

|  |   |
|--|---|
| What other tobacco product did you used today? | Not Applicable <input checked="" type="radio"/> |
|--|---|

---

|  |    |
|--|----|
| How many times did you use chewable/smokeless tobacco today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many cigars/cigarillos did you smoke today? | -9 |
|---|----|

---

|  |    |
|--|----|
| How many times did you smoke a pipe today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many times did you use a tobacco product today not listed previously? | -9 |
|---|----|

---

|   |    |
|---|----|
| How many times did you use an electronic cigarette today? | -9 |
|---|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (11)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

|   |                |
|---|----------------|
| Date of Birth   | (b) (6)        |
| Date of completion<br>DD/MMM/YYYY                       | 2014 FEB 01    |
| Time of completion<br>hh:mm                             | 18:38          |
| Date the questionnaire was completed for<br>DD/MMM/YYYY | 2014 FEB 01    |
| Assessment Status                                       | Completed      |
| What tobacco/nicotine product did you use today?        | THS 2.2 and CC |
| How many THS 2.2 tobacco sticks did you use today?      | 6              |
| How many CC/ roll-your-own did you smoke today?         | 2              |
| What NRT product did you used today?                    | Not Applicable |
| How many times did you use an inhaler today?            | -9             |
| How many times did you use a nasal spray today?         | -9             |
| How many gums did you use today?                        | -9             |
| How many lozenges did you use today?                    | -9             |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (11)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                     |    |
|-------------------------------------|----|
| How many patches did you use today? | -9 |
|-------------------------------------|----|

---

|  |    |
|--|----|
| How many times did you use other NRT products today not listed previously? | -9 |
|--|----|

---

|  |   |
|--|---|
| What other tobacco product did you used today? | Not Applicable <input checked="" type="radio"/> |
|--|---|

---

|  |    |
|--|----|
| How many times did you use chewable/smokeless tobacco today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many cigars/cigarillos did you smoke today? | -9 |
|---|----|

---

|  |    |
|--|----|
| How many times did you smoke a pipe today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many times did you use a tobacco product today not listed previously? | -9 |
|---|----|

---

|   |    |
|---|----|
| How many times did you use an electronic cigarette today? | -9 |
|---|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (12)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

|   |                |
|---|----------------|
| Date of Birth   | (b) (6)        |
| Date of completion<br>DD/MMM/YYYY                       | 2014 FEB 02    |
| Time of completion<br>hh:mm                             | 18:47          |
| Date the questionnaire was completed for<br>DD/MMM/YYYY | 2014 FEB 02    |
| Assessment Status                                       | Completed      |
| What tobacco/nicotine product did you use today?        | THS 2.2 and CC |
| How many THS 2.2 tobacco sticks did you use today?      | 9              |
| How many CC/ roll-your-own did you smoke today?         | 2              |
| What NRT product did you used today?                    | Not Applicable |
| How many times did you use an inhaler today?            | -9             |
| How many times did you use a nasal spray today?         | -9             |
| How many gums did you use today?                        | -9             |
| How many lozenges did you use today?                    | -9             |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (12)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                     |    |
|-------------------------------------|----|
| How many patches did you use today? | -9 |
|-------------------------------------|----|

---

|  |    |
|--|----|
| How many times did you use other NRT products today not listed previously? | -9 |
|--|----|

---

|  |   |
|--|---|
| What other tobacco product did you used today? | Not Applicable <input checked="" type="radio"/> |
|--|---|

---

|  |    |
|--|----|
| How many times did you use chewable/smokeless tobacco today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many cigars/cigarillos did you smoke today? | -9 |
|---|----|

---

|  |    |
|--|----|
| How many times did you smoke a pipe today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many times did you use a tobacco product today not listed previously? | -9 |
|---|----|

---

|   |    |
|---|----|
| How many times did you use an electronic cigarette today? | -9 |
|---|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (13)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

---

Date of Birth

(b) (6)

---

Date of completion  
DD/MMM/YYYY

2014 FEB 03

---

Time of completion  
hh:mm

18:47

---

Date the questionnaire was completed for  
DD/MMM/YYYY

2014 FEB 03

---

Assessment Status

Completed ☒

---

What tobacco/nicotine product did you use today?

THS 2.2 and CC ☒

---

How many THS 2.2 tobacco sticks did you use today?

9

---

How many CC/ roll-your-own did you smoke today?

2

---

What NRT product did you used today?

Not Applicable ☒

---

How many times did you use an inhaler today?

-9

---

How many times did you use a nasal spray today?

-9

---

How many gums did you use today?

-9

---

How many lozenges did you use today?

-9

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (13)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                     |    |
|-------------------------------------|----|
| How many patches did you use today? | -9 |
|-------------------------------------|----|

---

|  |    |
|--|----|
| How many times did you use other NRT products today not listed previously? | -9 |
|--|----|

---

|  |   |
|--|---|
| What other tobacco product did you used today? | Not Applicable <input checked="" type="radio"/> |
|--|---|

---

|  |    |
|--|----|
| How many times did you use chewable/smokeless tobacco today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many cigars/cigarillos did you smoke today? | -9 |
|---|----|

---

|  |    |
|--|----|
| How many times did you smoke a pipe today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many times did you use a tobacco product today not listed previously? | -9 |
|---|----|

---

|   |    |
|---|----|
| How many times did you use an electronic cigarette today? | -9 |
|---|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (14)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

|   |   |
|---|---|
| Date of Birth   | (b) (6)   |
| Date of completion<br>DD/MMM/YYYY                       | 2014 FEB 04                                     |
| Time of completion<br>hh:mm                             | 19:21   |
| Date the questionnaire was completed for<br>DD/MMM/YYYY | 2014 FEB 04                                     |
| Assessment Status                                       | Completed <input checked="" type="radio"/>      |
| What tobacco/nicotine product did you use today?        | THS 2.2 and CC <input checked="" type="radio"/> |
| How many THS 2.2 tobacco sticks did you use today?      | 8   |
| How many CC/ roll-your-own did you smoke today?         | 4   |
| What NRT product did you used today?                    | Not Applicable <input checked="" type="radio"/> |
| How many times did you use an inhaler today?            | -9  |
| How many times did you use a nasal spray today?         | -9  |
| How many gums did you use today?                        | -9  |
| How many lozenges did you use today?                    | -9  |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (14)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                     |    |
|-------------------------------------|----|
| How many patches did you use today? | -9 |
|-------------------------------------|----|

---

|  |    |
|--|----|
| How many times did you use other NRT products today not listed previously? | -9 |
|--|----|

---

|  |   |
|--|---|
| What other tobacco product did you used today? | Not Applicable <input checked="" type="radio"/> |
|--|---|

---

|  |    |
|--|----|
| How many times did you use chewable/smokeless tobacco today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many cigars/cigarillos did you smoke today? | -9 |
|---|----|

---

|  |    |
|--|----|
| How many times did you smoke a pipe today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many times did you use a tobacco product today not listed previously? | -9 |
|---|----|

---

|   |    |
|---|----|
| How many times did you use an electronic cigarette today? | -9 |
|---|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (15)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

---

Date of Birth

(b) (6)

---

Date of completion  
DD/MMM/YYYY

2014 FEB 05

---

Time of completion  
hh:mm

19:44

---

Date the questionnaire was completed for  
DD/MMM/YYYY

2014 FEB 05

---

Assessment Status

Completed ☒

---

What tobacco/nicotine product did you use today?

THS 2.2 ☒

---

How many THS 2.2 tobacco sticks did you use today?

5

---

How many CC/ roll-your-own did you smoke today?

-9

---

What NRT product did you used today?

Not Applicable ☒

---

How many times did you use an inhaler today?

-9

---

How many times did you use a nasal spray today?

-9

---

How many gums did you use today?

-9

---

How many lozenges did you use today?

-9

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (15)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                     |    |
|-------------------------------------|----|
| How many patches did you use today? | -9 |
|-------------------------------------|----|

---

|  |    |
|--|----|
| How many times did you use other NRT products today not listed previously? | -9 |
|--|----|

---

|  |   |
|--|---|
| What other tobacco product did you used today? | Not Applicable <input checked="" type="radio"/> |
|--|---|

---

|  |    |
|--|----|
| How many times did you use chewable/smokeless tobacco today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many cigars/cigarillos did you smoke today? | -9 |
|---|----|

---

|  |    |
|--|----|
| How many times did you smoke a pipe today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many times did you use a tobacco product today not listed previously? | -9 |
|---|----|

---

|   |    |
|---|----|
| How many times did you use an electronic cigarette today? | -9 |
|---|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (16)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

|   |   |
|---|---|
| Date of Birth   | (b) (6)   |
| Date of completion<br>DD/MMM/YYYY                       | 2014 FEB 06                                     |
| Time of completion<br>hh:mm                             | 20:02   |
| Date the questionnaire was completed for<br>DD/MMM/YYYY | 2014 FEB 06                                     |
| Assessment Status                                       | Completed <input checked="" type="radio"/>      |
| What tobacco/nicotine product did you use today?        | THS 2.2 and CC <input checked="" type="radio"/> |
| How many THS 2.2 tobacco sticks did you use today?      | 7   |
| How many CC/ roll-your-own did you smoke today?         | 2   |
| What NRT product did you used today?                    | Not Applicable <input checked="" type="radio"/> |
| How many times did you use an inhaler today?            | -9  |
| How many times did you use a nasal spray today?         | -9  |
| How many gums did you use today?                        | -9  |
| How many lozenges did you use today?                    | -9  |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (16)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                     |    |
|-------------------------------------|----|
| How many patches did you use today? | -9 |
|-------------------------------------|----|

---

|  |    |
|--|----|
| How many times did you use other NRT products today not listed previously? | -9 |
|--|----|

---

|  |   |
|--|---|
| What other tobacco product did you used today? | Not Applicable <input checked="" type="radio"/> |
|--|---|

---

|  |    |
|--|----|
| How many times did you use chewable/smokeless tobacco today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many cigars/cigarillos did you smoke today? | -9 |
|---|----|

---

|  |    |
|--|----|
| How many times did you smoke a pipe today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many times did you use a tobacco product today not listed previously? | -9 |
|---|----|

---

|   |    |
|---|----|
| How many times did you use an electronic cigarette today? | -9 |
|---|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (17)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

---

Date of Birth

(b) (6)

---

Date of completion  
DD/MMM/YYYY

2014 FEB 07

---

Time of completion  
hh:mm

18:37

---

Date the questionnaire was completed for  
DD/MMM/YYYY

2014 FEB 07

---

Assessment Status

Completed ☒

---

What tobacco/nicotine product did you use today?

THS 2.2 and CC ☒

---

How many THS 2.2 tobacco sticks did you use today?

5

---

How many CC/ roll-your-own did you smoke today?

2

---

What NRT product did you used today?

Not Applicable ☒

---

How many times did you use an inhaler today?

-9

---

How many times did you use a nasal spray today?

-9

---

How many gums did you use today?

-9

---

How many lozenges did you use today?

-9

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (17)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                     |    |
|-------------------------------------|----|
| How many patches did you use today? | -9 |
|-------------------------------------|----|

---

|  |    |
|--|----|
| How many times did you use other NRT products today not listed previously? | -9 |
|--|----|

---

|  |   |
|--|---|
| What other tobacco product did you used today? | Not Applicable <input checked="" type="radio"/> |
|--|---|

---

|  |    |
|--|----|
| How many times did you use chewable/smokeless tobacco today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many cigars/cigarillos did you smoke today? | -9 |
|---|----|

---

|  |    |
|--|----|
| How many times did you smoke a pipe today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many times did you use a tobacco product today not listed previously? | -9 |
|---|----|

---

|   |    |
|---|----|
| How many times did you use an electronic cigarette today? | -9 |
|---|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (18)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

|   |                |
|---|----------------|
| Date of Birth   | (b) (6)        |
| Date of completion<br>DD/MMM/YYYY                       | 2014 FEB 08    |
| Time of completion<br>hh:mm                             | 19:09          |
| Date the questionnaire was completed for<br>DD/MMM/YYYY | 2014 FEB 08    |
| Assessment Status                                       | Completed      |
| What tobacco/nicotine product did you use today?        | THS 2.2 and CC |
| How many THS 2.2 tobacco sticks did you use today?      | 6              |
| How many CC/ roll-your-own did you smoke today?         | 4              |
| What NRT product did you used today?                    | Not Applicable |
| How many times did you use an inhaler today?            | -9             |
| How many times did you use a nasal spray today?         | -9             |
| How many gums did you use today?                        | -9             |
| How many lozenges did you use today?                    | -9             |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (18)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                     |    |
|-------------------------------------|----|
| How many patches did you use today? | -9 |
|-------------------------------------|----|

---

|  |    |
|--|----|
| How many times did you use other NRT products today not listed previously? | -9 |
|--|----|

---

|  |   |
|--|---|
| What other tobacco product did you used today? | Not Applicable <input checked="" type="radio"/> |
|--|---|

---

|  |    |
|--|----|
| How many times did you use chewable/smokeless tobacco today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many cigars/cigarillos did you smoke today? | -9 |
|---|----|

---

|  |    |
|--|----|
| How many times did you smoke a pipe today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many times did you use a tobacco product today not listed previously? | -9 |
|---|----|

---

|   |    |
|---|----|
| How many times did you use an electronic cigarette today? | -9 |
|---|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (19)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

|   |                |
|---|----------------|
| Date of Birth   | (b) (6)        |
| Date of completion<br>DD/MMM/YYYY                       | 2014 FEB 09    |
| Time of completion<br>hh:mm                             | 18:44          |
| Date the questionnaire was completed for<br>DD/MMM/YYYY | 2014 FEB 09    |
| Assessment Status                                       | Completed      |
| What tobacco/nicotine product did you use today?        | THS 2.2 and CC |
| How many THS 2.2 tobacco sticks did you use today?      | 5              |
| How many CC/ roll-your-own did you smoke today?         | 4              |
| What NRT product did you used today?                    | Not Applicable |
| How many times did you use an inhaler today?            | -9             |
| How many times did you use a nasal spray today?         | -9             |
| How many gums did you use today?                        | -9             |
| How many lozenges did you use today?                    | -9             |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (19)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                     |    |
|-------------------------------------|----|
| How many patches did you use today? | -9 |
|-------------------------------------|----|

---

|  |    |
|--|----|
| How many times did you use other NRT products today not listed previously? | -9 |
|--|----|

---

|  |   |
|--|---|
| What other tobacco product did you used today? | Not Applicable <input checked="" type="radio"/> |
|--|---|

---

|  |    |
|--|----|
| How many times did you use chewable/smokeless tobacco today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many cigars/cigarillos did you smoke today? | -9 |
|---|----|

---

|  |    |
|--|----|
| How many times did you smoke a pipe today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many times did you use a tobacco product today not listed previously? | -9 |
|---|----|

---

|   |    |
|---|----|
| How many times did you use an electronic cigarette today? | -9 |
|---|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (20)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

|   |                |
|---|----------------|
| Date of Birth   | (b) (6)        |
| Date of completion<br>DD/MMM/YYYY                       | 2014 FEB 10    |
| Time of completion<br>hh:mm                             | 18:31          |
| Date the questionnaire was completed for<br>DD/MMM/YYYY | 2014 FEB 10    |
| Assessment Status                                       | Completed      |
| What tobacco/nicotine product did you use today?        | THS 2.2 and CC |
| How many THS 2.2 tobacco sticks did you use today?      | 4              |
| How many CC/ roll-your-own did you smoke today?         | 3              |
| What NRT product did you used today?                    | Not Applicable |
| How many times did you use an inhaler today?            | -9             |
| How many times did you use a nasal spray today?         | -9             |
| How many gums did you use today?                        | -9             |
| How many lozenges did you use today?                    | -9             |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (20)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                     |    |
|-------------------------------------|----|
| How many patches did you use today? | -9 |
|-------------------------------------|----|

---

|  |    |
|--|----|
| How many times did you use other NRT products today not listed previously? | -9 |
|--|----|

---

|  |   |
|--|---|
| What other tobacco product did you used today? | Not Applicable <input checked="" type="radio"/> |
|--|---|

---

|  |    |
|--|----|
| How many times did you use chewable/smokeless tobacco today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many cigars/cigarillos did you smoke today? | -9 |
|---|----|

---

|  |    |
|--|----|
| How many times did you smoke a pipe today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many times did you use a tobacco product today not listed previously? | -9 |
|---|----|

---

|   |    |
|---|----|
| How many times did you use an electronic cigarette today? | -9 |
|---|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (21)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

|   |   |
|---|---|
| Date of Birth   | (b) (6)   |
| Date of completion<br>DD/MMM/YYYY                       | 2014 FEB 11                                     |
| Time of completion<br>hh:mm                             | 18:37   |
| Date the questionnaire was completed for<br>DD/MMM/YYYY | 2014 FEB 11                                     |
| Assessment Status                                       | Completed <input checked="" type="radio"/>      |
| What tobacco/nicotine product did you use today?        | THS 2.2 and CC <input checked="" type="radio"/> |
| How many THS 2.2 tobacco sticks did you use today?      | 4   |
| How many CC/ roll-your-own did you smoke today?         | 2   |
| What NRT product did you used today?                    | Not Applicable <input checked="" type="radio"/> |
| How many times did you use an inhaler today?            | -9  |
| How many times did you use a nasal spray today?         | -9  |
| How many gums did you use today?                        | -9  |
| How many lozenges did you use today?                    | -9  |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (21)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                     |    |
|-------------------------------------|----|
| How many patches did you use today? | -9 |
|-------------------------------------|----|

---

|  |    |
|--|----|
| How many times did you use other NRT products today not listed previously? | -9 |
|--|----|

---

|  |   |
|--|---|
| What other tobacco product did you used today? | Not Applicable <input checked="" type="radio"/> |
|--|---|

---

|  |    |
|--|----|
| How many times did you use chewable/smokeless tobacco today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many cigars/cigarillos did you smoke today? | -9 |
|---|----|

---

|  |    |
|--|----|
| How many times did you smoke a pipe today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many times did you use a tobacco product today not listed previously? | -9 |
|---|----|

---

|   |    |
|---|----|
| How many times did you use an electronic cigarette today? | -9 |
|---|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (22)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

|   |   |
|---|---|
| Date of Birth   | (b) (6)   |
| Date of completion<br>DD/MMM/YYYY                       | 2014 FEB 12                                     |
| Time of completion<br>hh:mm                             | 18:54   |
| Date the questionnaire was completed for<br>DD/MMM/YYYY | 2014 FEB 12                                     |
| Assessment Status                                       | Completed <input checked="" type="radio"/>      |
| What tobacco/nicotine product did you use today?        | THS 2.2 <input checked="" type="radio"/>        |
| How many THS 2.2 tobacco sticks did you use today?      | 3   |
| How many CC/ roll-your-own did you smoke today?         | -9  |
| What NRT product did you used today?                    | Not Applicable <input checked="" type="radio"/> |
| How many times did you use an inhaler today?            | -9  |
| How many times did you use a nasal spray today?         | -9  |
| How many gums did you use today?                        | -9  |
| How many lozenges did you use today?                    | -9  |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (22)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                     |    |
|-------------------------------------|----|
| How many patches did you use today? | -9 |
|-------------------------------------|----|

---

|  |    |
|--|----|
| How many times did you use other NRT products today not listed previously? | -9 |
|--|----|

---

|  |   |
|--|---|
| What other tobacco product did you used today? | Not Applicable <input checked="" type="radio"/> |
|--|---|

---

|  |    |
|--|----|
| How many times did you use chewable/smokeless tobacco today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many cigars/cigarillos did you smoke today? | -9 |
|---|----|

---

|  |    |
|--|----|
| How many times did you smoke a pipe today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many times did you use a tobacco product today not listed previously? | -9 |
|---|----|

---

|   |    |
|---|----|
| How many times did you use an electronic cigarette today? | -9 |
|---|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (23)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

|   |   |
|---|---|
| Date of Birth   | (b) (6)   |
| Date of completion<br>DD/MMM/YYYY                       | 2014 FEB 13                                     |
| Time of completion<br>hh:mm                             | 20:01   |
| Date the questionnaire was completed for<br>DD/MMM/YYYY | 2014 FEB 13                                     |
| Assessment Status                                       | Completed <input checked="" type="radio"/>      |
| What tobacco/nicotine product did you use today?        | THS 2.2 and CC <input checked="" type="radio"/> |
| How many THS 2.2 tobacco sticks did you use today?      | 5   |
| How many CC/ roll-your-own did you smoke today?         | 3   |
| What NRT product did you used today?                    | Not Applicable <input checked="" type="radio"/> |
| How many times did you use an inhaler today?            | -9  |
| How many times did you use a nasal spray today?         | -9  |
| How many gums did you use today?                        | -9  |
| How many lozenges did you use today?                    | -9  |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (23)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                     |    |
|-------------------------------------|----|
| How many patches did you use today? | -9 |
|-------------------------------------|----|

---

|  |    |
|--|----|
| How many times did you use other NRT products today not listed previously? | -9 |
|--|----|

---

|  |   |
|--|---|
| What other tobacco product did you used today? | Not Applicable <input checked="" type="radio"/> |
|--|---|

---

|  |    |
|--|----|
| How many times did you use chewable/smokeless tobacco today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many cigars/cigarillos did you smoke today? | -9 |
|---|----|

---

|  |    |
|--|----|
| How many times did you smoke a pipe today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many times did you use a tobacco product today not listed previously? | -9 |
|---|----|

---

|   |    |
|---|----|
| How many times did you use an electronic cigarette today? | -9 |
|---|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (24)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

|   |   |
|---|---|
| Date of Birth   | (b) (6)   |
| Date of completion<br>DD/MMM/YYYY                       | 2014 FEB 14                                     |
| Time of completion<br>hh:mm                             | 19:43   |
| Date the questionnaire was completed for<br>DD/MMM/YYYY | 2014 FEB 14                                     |
| Assessment Status                                       | Completed <input checked="" type="radio"/>      |
| What tobacco/nicotine product did you use today?        | THS 2.2 and CC <input checked="" type="radio"/> |
| How many THS 2.2 tobacco sticks did you use today?      | 3   |
| How many CC/ roll-your-own did you smoke today?         | 3   |
| What NRT product did you used today?                    | Not Applicable <input checked="" type="radio"/> |
| How many times did you use an inhaler today?            | -9  |
| How many times did you use a nasal spray today?         | -9  |
| How many gums did you use today?                        | -9  |
| How many lozenges did you use today?                    | -9  |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (24)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                     |    |
|-------------------------------------|----|
| How many patches did you use today? | -9 |
|-------------------------------------|----|

---

|  |    |
|--|----|
| How many times did you use other NRT products today not listed previously? | -9 |
|--|----|

---

|  |   |
|--|---|
| What other tobacco product did you used today? | Not Applicable <input checked="" type="radio"/> |
|--|---|

---

|  |    |
|--|----|
| How many times did you use chewable/smokeless tobacco today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many cigars/cigarillos did you smoke today? | -9 |
|---|----|

---

|  |    |
|--|----|
| How many times did you smoke a pipe today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many times did you use a tobacco product today not listed previously? | -9 |
|---|----|

---

|   |    |
|---|----|
| How many times did you use an electronic cigarette today? | -9 |
|---|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (25)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

|   |                |
|---|----------------|
| Date of Birth   | (b) (6)        |
| Date of completion<br>DD/MMM/YYYY                       | 2014 FEB 15    |
| Time of completion<br>hh:mm                             | 20:00          |
| Date the questionnaire was completed for<br>DD/MMM/YYYY | 2014 FEB 15    |
| Assessment Status                                       | Completed      |
| What tobacco/nicotine product did you use today?        | THS 2.2 and CC |
| How many THS 2.2 tobacco sticks did you use today?      | 4              |
| How many CC/ roll-your-own did you smoke today?         | 4              |
| What NRT product did you used today?                    | Not Applicable |
| How many times did you use an inhaler today?            | -9             |
| How many times did you use a nasal spray today?         | -9             |
| How many gums did you use today?                        | -9             |
| How many lozenges did you use today?                    | -9             |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (25)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                     |    |
|-------------------------------------|----|
| How many patches did you use today? | -9 |
|-------------------------------------|----|

---

|  |    |
|--|----|
| How many times did you use other NRT products today not listed previously? | -9 |
|--|----|

---

|  |   |
|--|---|
| What other tobacco product did you used today? | Not Applicable <input checked="" type="radio"/> |
|--|---|

---

|  |    |
|--|----|
| How many times did you use chewable/smokeless tobacco today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many cigars/cigarillos did you smoke today? | -9 |
|---|----|

---

|  |    |
|--|----|
| How many times did you smoke a pipe today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many times did you use a tobacco product today not listed previously? | -9 |
|---|----|

---

|   |    |
|---|----|
| How many times did you use an electronic cigarette today? | -9 |
|---|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Form: Product use diary (26)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

|   |   |
|---|---|
| Date of Birth   | (b) (6)   |
| Date of completion<br>DD/MMM/YYYY                       | 2014 FEB 16                                     |
| Time of completion<br>hh:mm                             | 19:00   |
| Date the questionnaire was completed for<br>DD/MMM/YYYY | 2014 FEB 16                                     |
| Assessment Status                                       | Completed <input checked="" type="radio"/>      |
| What tobacco/nicotine product did you use today?        | THS 2.2 and CC <input checked="" type="radio"/> |
| How many THS 2.2 tobacco sticks did you use today?      | 3   |
| How many CC/ roll-your-own did you smoke today?         | 4   |
| What NRT product did you used today?                    | Not Applicable <input checked="" type="radio"/> |
| How many times did you use an inhaler today?            | -9  |
| How many times did you use a nasal spray today?         | -9  |
| How many gums did you use today?                        | -9  |
| How many lozenges did you use today?                    | -9  |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (26)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                     |    |
|-------------------------------------|----|
| How many patches did you use today? | -9 |
|-------------------------------------|----|

---

|  |    |
|--|----|
| How many times did you use other NRT products today not listed previously? | -9 |
|--|----|

---

|  |   |
|--|---|
| What other tobacco product did you used today? | Not Applicable <input checked="" type="radio"/> |
|--|---|

---

|  |    |
|--|----|
| How many times did you use chewable/smokeless tobacco today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many cigars/cigarillos did you smoke today? | -9 |
|---|----|

---

|  |    |
|--|----|
| How many times did you smoke a pipe today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many times did you use a tobacco product today not listed previously? | -9 |
|---|----|

---

|   |    |
|---|----|
| How many times did you use an electronic cigarette today? | -9 |
|---|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (27)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

|   |   |
|---|---|
| Date of Birth   | (b) (6)   |
| Date of completion<br>DD/MMM/YYYY                       | 2014 FEB 17                                     |
| Time of completion<br>hh:mm                             | 19:16   |
| Date the questionnaire was completed for<br>DD/MMM/YYYY | 2014 FEB 17                                     |
| Assessment Status                                       | Completed <input checked="" type="radio"/>      |
| What tobacco/nicotine product did you use today?        | THS 2.2 and CC <input checked="" type="radio"/> |
| How many THS 2.2 tobacco sticks did you use today?      | 5   |
| How many CC/ roll-your-own did you smoke today?         | 4   |
| What NRT product did you used today?                    | Not Applicable <input checked="" type="radio"/> |
| How many times did you use an inhaler today?            | -9  |
| How many times did you use a nasal spray today?         | -9  |
| How many gums did you use today?                        | -9  |
| How many lozenges did you use today?                    | -9  |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (27)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                     |    |
|-------------------------------------|----|
| How many patches did you use today? | -9 |
|-------------------------------------|----|

---

|  |    |
|--|----|
| How many times did you use other NRT products today not listed previously? | -9 |
|--|----|

---

|  |   |
|--|---|
| What other tobacco product did you used today? | Not Applicable <input checked="" type="radio"/> |
|--|---|

---

|  |    |
|--|----|
| How many times did you use chewable/smokeless tobacco today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many cigars/cigarillos did you smoke today? | -9 |
|---|----|

---

|  |    |
|--|----|
| How many times did you smoke a pipe today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many times did you use a tobacco product today not listed previously? | -9 |
|---|----|

---

|   |    |
|---|----|
| How many times did you use an electronic cigarette today? | -9 |
|---|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (28)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

|   |                |
|---|----------------|
| Date of Birth   | (b) (6)        |
| Date of completion<br>DD/MMM/YYYY                       | 2014 FEB 18    |
| Time of completion<br>hh:mm                             | 19:35          |
| Date the questionnaire was completed for<br>DD/MMM/YYYY | 2014 FEB 18    |
| Assessment Status                                       | Completed      |
| What tobacco/nicotine product did you use today?        | THS 2.2 and CC |
| How many THS 2.2 tobacco sticks did you use today?      | 5              |
| How many CC/ roll-your-own did you smoke today?         | 4              |
| What NRT product did you used today?                    | Not Applicable |
| How many times did you use an inhaler today?            | -9             |
| How many times did you use a nasal spray today?         | -9             |
| How many gums did you use today?                        | -9             |
| How many lozenges did you use today?                    | -9             |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (28)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                     |    |
|-------------------------------------|----|
| How many patches did you use today? | -9 |
|-------------------------------------|----|

---

|  |    |
|--|----|
| How many times did you use other NRT products today not listed previously? | -9 |
|--|----|

---

|  |   |
|--|---|
| What other tobacco product did you used today? | Not Applicable <input checked="" type="radio"/> |
|--|---|

---

|  |    |
|--|----|
| How many times did you use chewable/smokeless tobacco today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many cigars/cigarillos did you smoke today? | -9 |
|---|----|

---

|  |    |
|--|----|
| How many times did you smoke a pipe today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many times did you use a tobacco product today not listed previously? | -9 |
|---|----|

---

|   |    |
|---|----|
| How many times did you use an electronic cigarette today? | -9 |
|---|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (29)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

---

Date of Birth

(b) (6)

---

Date of completion  
DD/MMM/YYYY

2014 FEB 19

---

Time of completion  
hh:mm

19:46

---

Date the questionnaire was completed for  
DD/MMM/YYYY

2014 FEB 19

---

Assessment Status

Completed ☒

---

What tobacco/nicotine product did you use today?

THS 2.2 and CC ☒

---

How many THS 2.2 tobacco sticks did you use today?

4

---

How many CC/ roll-your-own did you smoke today?

4

---

What NRT product did you used today?

Not Applicable ☒

---

How many times did you use an inhaler today?

-9

---

How many times did you use a nasal spray today?

-9

---

How many gums did you use today?

-9

---

How many lozenges did you use today?

-9

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (29)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                     |    |
|-------------------------------------|----|
| How many patches did you use today? | -9 |
|-------------------------------------|----|

---

|  |    |
|--|----|
| How many times did you use other NRT products today not listed previously? | -9 |
|--|----|

---

|  |   |
|--|---|
| What other tobacco product did you used today? | Not Applicable <input checked="" type="radio"/> |
|--|---|

---

|  |    |
|--|----|
| How many times did you use chewable/smokeless tobacco today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many cigars/cigarillos did you smoke today? | -9 |
|---|----|

---

|  |    |
|--|----|
| How many times did you smoke a pipe today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many times did you use a tobacco product today not listed previously? | -9 |
|---|----|

---

|   |    |
|---|----|
| How many times did you use an electronic cigarette today? | -9 |
|---|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Form: Product use diary (30)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

---

Date of Birth

(b) (6)

---

Date of completion  
DD/MMM/YYYY

2014 FEB 20

---

Time of completion  
hh:mm

20:01

---

Date the questionnaire was completed for  
DD/MMM/YYYY

2014 FEB 20

---

Assessment Status

Completed ☒

---

What tobacco/nicotine product did you use today?

THS 2.2 and CC ☒

---

How many THS 2.2 tobacco sticks did you use today?

3

---

How many CC/ roll-your-own did you smoke today?

4

---

What NRT product did you used today?

Not Applicable ☒

---

How many times did you use an inhaler today?

-9

---

How many times did you use a nasal spray today?

-9

---

How many gums did you use today?

-9

---

How many lozenges did you use today?

-9

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (30)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                     |    |
|-------------------------------------|----|
| How many patches did you use today? | -9 |
|-------------------------------------|----|

---

|  |    |
|--|----|
| How many times did you use other NRT products today not listed previously? | -9 |
|--|----|

---

|  |   |
|--|---|
| What other tobacco product did you used today? | Not Applicable <input checked="" type="radio"/> |
|--|---|

---

|  |    |
|--|----|
| How many times did you use chewable/smokeless tobacco today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many cigars/cigarillos did you smoke today? | -9 |
|---|----|

---

|  |    |
|--|----|
| How many times did you smoke a pipe today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many times did you use a tobacco product today not listed previously? | -9 |
|---|----|

---

|   |    |
|---|----|
| How many times did you use an electronic cigarette today? | -9 |
|---|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (31)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

---

Date of Birth

(b) (6)

---

Date of completion  
DD/MMM/YYYY

2014 FEB 21

---

Time of completion  
hh:mm

19:46

---

Date the questionnaire was completed for  
DD/MMM/YYYY

2014 FEB 21

---

Assessment Status

Completed ☒

---

What tobacco/nicotine product did you use today?

THS 2.2 and CC ☒

---

How many THS 2.2 tobacco sticks did you use today?

3

---

How many CC/ roll-your-own did you smoke today?

3

---

What NRT product did you used today?

Not Applicable ☒

---

How many times did you use an inhaler today?

-9

---

How many times did you use a nasal spray today?

-9

---

How many gums did you use today?

-9

---

How many lozenges did you use today?

-9

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (31)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                     |    |
|-------------------------------------|----|
| How many patches did you use today? | -9 |
|-------------------------------------|----|

---

|  |    |
|--|----|
| How many times did you use other NRT products today not listed previously? | -9 |
|--|----|

---

|  |   |
|--|---|
| What other tobacco product did you used today? | Not Applicable <input checked="" type="radio"/> |
|--|---|

---

|  |    |
|--|----|
| How many times did you use chewable/smokeless tobacco today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many cigars/cigarillos did you smoke today? | -9 |
|---|----|

---

|  |    |
|--|----|
| How many times did you smoke a pipe today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many times did you use a tobacco product today not listed previously? | -9 |
|---|----|

---

|   |    |
|---|----|
| How many times did you use an electronic cigarette today? | -9 |
|---|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Form: Product use diary (32)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

|   |   |
|---|---|
| Date of Birth   | (b) (6)   |
| Date of completion<br>DD/MMM/YYYY                       | 2014 FEB 22                                     |
| Time of completion<br>hh:mm                             | 19:00   |
| Date the questionnaire was completed for<br>DD/MMM/YYYY | 2014 FEB 22                                     |
| Assessment Status                                       | Completed <input checked="" type="radio"/>      |
| What tobacco/nicotine product did you use today?        | THS 2.2 and CC <input checked="" type="radio"/> |
| How many THS 2.2 tobacco sticks did you use today?      | 4   |
| How many CC/ roll-your-own did you smoke today?         | 5   |
| What NRT product did you used today?                    | Not Applicable <input checked="" type="radio"/> |
| How many times did you use an inhaler today?            | -9  |
| How many times did you use a nasal spray today?         | -9  |
| How many gums did you use today?                        | -9  |
| How many lozenges did you use today?                    | -9  |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (32)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                     |    |
|-------------------------------------|----|
| How many patches did you use today? | -9 |
|-------------------------------------|----|

---

|  |    |
|--|----|
| How many times did you use other NRT products today not listed previously? | -9 |
|--|----|

---

|  |   |
|--|---|
| What other tobacco product did you used today? | Not Applicable <input checked="" type="radio"/> |
|--|---|

---

|  |    |
|--|----|
| How many times did you use chewable/smokeless tobacco today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many cigars/cigarillos did you smoke today? | -9 |
|---|----|

---

|  |    |
|--|----|
| How many times did you smoke a pipe today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many times did you use a tobacco product today not listed previously? | -9 |
|---|----|

---

|   |    |
|---|----|
| How many times did you use an electronic cigarette today? | -9 |
|---|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Form: Product use diary (33)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

---

Date of Birth

(b) (6)

---

Date of completion  
DD/MMM/YYYY

2014 FEB 23

---

Time of completion  
hh:mm

18:46

---

Date the questionnaire was completed for  
DD/MMM/YYYY

2014 FEB 23

---

Assessment Status

Completed ☒

---

What tobacco/nicotine product did you use today?

THS 2.2 and CC ☒

---

How many THS 2.2 tobacco sticks did you use today?

4

---

How many CC/ roll-your-own did you smoke today?

4

---

What NRT product did you used today?

Not Applicable ☒

---

How many times did you use an inhaler today?

-9

---

How many times did you use a nasal spray today?

-9

---

How many gums did you use today?

-9

---

How many lozenges did you use today?

-9

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (33)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                     |    |
|-------------------------------------|----|
| How many patches did you use today? | -9 |
|-------------------------------------|----|

---

|  |    |
|--|----|
| How many times did you use other NRT products today not listed previously? | -9 |
|--|----|

---

|  |   |
|--|---|
| What other tobacco product did you used today? | Not Applicable <input checked="" type="radio"/> |
|--|---|

---

|  |    |
|--|----|
| How many times did you use chewable/smokeless tobacco today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many cigars/cigarillos did you smoke today? | -9 |
|---|----|

---

|  |    |
|--|----|
| How many times did you smoke a pipe today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many times did you use a tobacco product today not listed previously? | -9 |
|---|----|

---

|   |    |
|---|----|
| How many times did you use an electronic cigarette today? | -9 |
|---|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (34)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

---

Date of Birth

(b) (6)

---

Date of completion  
DD/MMM/YYYY

2014 FEB 24

---

Time of completion  
hh:mm

18:41

---

Date the questionnaire was completed for  
DD/MMM/YYYY

2014 FEB 24

---

Assessment Status

Completed ☒

---

What tobacco/nicotine product did you use today?

THS 2.2 and CC ☒

---

How many THS 2.2 tobacco sticks did you use today?

4

---

How many CC/ roll-your-own did you smoke today?

5

---

What NRT product did you used today?

Not Applicable ☒

---

How many times did you use an inhaler today?

-9

---

How many times did you use a nasal spray today?

-9

---

How many gums did you use today?

-9

---

How many lozenges did you use today?

-9

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (34)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                     |    |
|-------------------------------------|----|
| How many patches did you use today? | -9 |
|-------------------------------------|----|

---

|  |    |
|--|----|
| How many times did you use other NRT products today not listed previously? | -9 |
|--|----|

---

|  |   |
|--|---|
| What other tobacco product did you used today? | Not Applicable <input checked="" type="radio"/> |
|--|---|

---

|  |    |
|--|----|
| How many times did you use chewable/smokeless tobacco today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many cigars/cigarillos did you smoke today? | -9 |
|---|----|

---

|  |    |
|--|----|
| How many times did you smoke a pipe today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many times did you use a tobacco product today not listed previously? | -9 |
|---|----|

---

|   |    |
|---|----|
| How many times did you use an electronic cigarette today? | -9 |
|---|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (35)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

|   |                |
|---|----------------|
| Date of Birth   | (b) (6)        |
| Date of completion<br>DD/MMM/YYYY                       | 2014 FEB 25    |
| Time of completion<br>hh:mm                             | 20:01          |
| Date the questionnaire was completed for<br>DD/MMM/YYYY | 2014 FEB 25    |
| Assessment Status                                       | Completed      |
| What tobacco/nicotine product did you use today?        | THS 2.2 and CC |
| How many THS 2.2 tobacco sticks did you use today?      | 5              |
| How many CC/ roll-your-own did you smoke today?         | 4              |
| What NRT product did you used today?                    | Not Applicable |
| How many times did you use an inhaler today?            | -9             |
| How many times did you use a nasal spray today?         | -9             |
| How many gums did you use today?                        | -9             |
| How many lozenges did you use today?                    | -9             |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Product use diary (35)**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:25**

**Generated On: 20 Jul 2016 11:47:42**

---

|                                     |    |
|-------------------------------------|----|
| How many patches did you use today? | -9 |
|-------------------------------------|----|

---

|  |    |
|--|----|
| How many times did you use other NRT products today not listed previously? | -9 |
|--|----|

---

|  |   |
|--|---|
| What other tobacco product did you used today? | Not Applicable <input checked="" type="radio"/> |
|--|---|

---

|  |    |
|--|----|
| How many times did you use chewable/smokeless tobacco today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many cigars/cigarillos did you smoke today? | -9 |
|---|----|

---

|  |    |
|--|----|
| How many times did you smoke a pipe today? | -9 |
|--|----|

---

|   |    |
|---|----|
| How many times did you use a tobacco product today not listed previously? | -9 |
|---|----|

---

|   |    |
|---|----|
| How many times did you use an electronic cigarette today? | -9 |
|---|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1042**

**Form: End of study**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:24**

**Generated On: 20 Jul 2016 11:47:42**

---

End of study date

26 FEB 2014  
DD/MMM/YYYY

---

Has the subject completed the study ?

No ☒

---

If No, please specify the reason:

Withdrawal by Subject ☒

---

Details:

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1042**

**Form: Withdrawal**

**Data signed: (hfarmer1) 26 Mar 2015 14:45:24**

**Generated On: 20 Jul 2016 11:47:42**

---

|                    |                         |
|--------------------|-------------------------|
| Date of withdrawal | 26 FEB 2014 DD/MMM/YYYY |
|--------------------|-------------------------|

---

|  |                                      |
|--|--------------------------------------|
| Did the subject withdraw it's consent from the main study? | Yes <input checked="" type="radio"/> |
|--|--------------------------------------|

---

|                                      |                              |
|--------------------------------------|------------------------------|
| If available, please provide details | THE SUBJECT WITHDREW CONSENT |
|--------------------------------------|------------------------------|

---

|   |                                      |
|---|--------------------------------------|
| Did the subject withdraw from the Protected Health Information (PHI)? | Yes <input checked="" type="radio"/> |
|---|--------------------------------------|

---

|  |                                     |
|--|-------------------------------------|
| Did the subject confirm that samples collected up to the time of withdrawal can be analysed? | No <input checked="" type="radio"/> |
|--|-------------------------------------|

---