

Subject Case Report Forms

1194 (Prod: Covance Clinical Development Services, Daytona Beach, Florida)

Generated On: 20 Jul 2016 16:57:04

All time stamps listed in this document are displayed in GMT

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Form: Subject**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:53**

**Generated On: 20 Jul 2016 16:57:04**

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|                  |      |
|------------------|------|
| Screening number | 1194 |
|------------------|------|

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

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Subject Status**

**Form: Subject Status**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:05**

**Generated On: 20 Jul 2016 16:57:04**

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Date of 'Screen Failed' Event

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Date of 'Discontinued From  
Enrollment' Event

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Randomization Date

08 MAR 2014  
DD/MMM/YYYY

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Randomization Time

10:06  
hour:min 24-hour clock

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

**Form: Date of Visit**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:10**

**Generated On: 20 Jul 2016 16:57:04**

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Date of Visit

25 FEB 2014  
DD/MMM/YYYY

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

**Form: Additional Informed Consent**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:05**

**Generated On: 20 Jul 2016 16:57:04**

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

Yes ☒

---

Consent Date

25 FEB 2014  
DD/MMM/YYYY

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

Yes ☒

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Consent Date

25 FEB 2014  
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

**Form: Inclusion Criteria**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:06**

**Generated On: 20 Jul 2016 16:57:04**

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

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

**Form: Inclusion Criteria (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:06**

**Generated On: 20 Jul 2016 16:57:04**

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

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|                     |   |
|---------------------|---|
| 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. |
|---------------------|---|

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

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

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

**Form: Inclusion Criteria (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:06**

**Generated On: 20 Jul 2016 16:57:04**

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

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|                     |  |
|---------------------|--|
| Inclusion Criterion | Subject is at a minimum 22<br>years of age(inclusive). |
|---------------------|--|

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

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

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

**Form: Inclusion Criteria (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:06**

**Generated On: 20 Jul 2016 16:57:04**

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Inclusion Criterion Number

3

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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).

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Result

Yes

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

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Screening**

**Form: Inclusion Criteria (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:06**

**Generated On: 20 Jul 2016 16:57:04**

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

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|                     |   |
|---------------------|---|
| 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). |
|---------------------|---|

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

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

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

**Form: Inclusion Criteria (5)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:06**

**Generated On: 20 Jul 2016 16:57:04**

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

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

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

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

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

**Form: Inclusion Criteria (6)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:06**

**Generated On: 20 Jul 2016 16:57:04**

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

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|                     |   |
|---------------------|---|
| 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 ). |
|---------------------|---|

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

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

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

**Form: Exclusion Criteria**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:05**

**Generated On: 20 Jul 2016 16:57:04**

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

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

**Form: Exclusion Criteria (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:05**

**Generated On: 20 Jul 2016 16:57:04**

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

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

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

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

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Screening**

**Form: Exclusion Criteria (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:05**

**Generated On: 20 Jul 2016 16:57:04**

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

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|                     |  |
|---------------------|--|
| 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). |
|---------------------|--|

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

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

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Screening**

**Form: Exclusion Criteria (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:05**

**Generated On: 20 Jul 2016 16:57:04**

---

Exclusion Criterion Number

3

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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.

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Result

No

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

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

**Form: Exclusion Criteria (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:05**

**Generated On: 20 Jul 2016 16:57:04**

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

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|                     |   |
|---------------------|---|
| 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). |
|---------------------|---|

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

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

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

**Form: Exclusion Criteria (5)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:05**

**Generated On: 20 Jul 2016 16:57:04**

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

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

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

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

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

**Form: Exclusion Criteria (6)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:05**

**Generated On: 20 Jul 2016 16:57:04**

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

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|                     |   |
|---------------------|---|
| 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. |
|---------------------|---|

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

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

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

**Form: Exclusion Criteria (7)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:05**

**Generated On: 20 Jul 2016 16:57:04**

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

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

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

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

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

**Form: Exclusion Criteria (8)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:05**

**Generated On: 20 Jul 2016 16:57:04**

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

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|                     |   |
|---------------------|---|
| 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. |
|---------------------|---|

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

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

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

**Form: Exclusion Criteria (9)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:05**

**Generated On: 20 Jul 2016 16:57:04**

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

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|                     |  |
|---------------------|--|
| 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. |
|---------------------|--|

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

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

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Screening**

**Form: Exclusion Criteria (10)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:05**

**Generated On: 20 Jul 2016 16:57:04**

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

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|                     |   |
|---------------------|---|
| 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. |
|---------------------|---|

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

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

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Screening**

**Form: Exclusion Criteria (11)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:05**

**Generated On: 20 Jul 2016 16:57:04**

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

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|                     |   |
|---------------------|---|
| 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> |
|---------------------|---|

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

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

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

**Form: Exclusion Criteria (12)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:05**

**Generated On: 20 Jul 2016 16:57:04**

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

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

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

---

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

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

**Form: Exclusion Criteria (13)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:05**

**Generated On: 20 Jul 2016 16:57:04**

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

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|                     |   |
|---------------------|---|
| 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. |
|---------------------|---|

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

---

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

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

**Form: Exclusion Criteria (14)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:05**

**Generated On: 20 Jul 2016 16:57:04**

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

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

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

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

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

**Form: Exclusion Criteria (15)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:05**

**Generated On: 20 Jul 2016 16:57:04**

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

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

---

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

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

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

**Form: Exclusion Criteria (16)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:05**

**Generated On: 20 Jul 2016 16:57:04**

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

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|                     |  |                                  |
|---------------------|--|----------------------------------|
| 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.

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

**Form: Exclusion Criteria (17)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:05**

**Generated On: 20 Jul 2016 16:57:04**

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

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|                     |  |
|---------------------|--|
| 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 |
|--------|----|

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

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

**Form: Exclusion Criteria (18)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:05**

**Generated On: 20 Jul 2016 16:57:04**

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|                            |    |
|----------------------------|----|
| 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 |
|--------|----|

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

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

**Form: Exclusion Criteria (19)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:05**

**Generated On: 20 Jul 2016 16:57:04**

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

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

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

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

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

**Form: Exclusion Criteria (20)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:05**

**Generated On: 20 Jul 2016 16:57:04**

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

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|                     |  |
|---------------------|--|
| Exclusion Criterion | For women only: Subject is pregnant (does not have negative pregnancy tests at Screening and at Admission) or is breast feeding. |
|---------------------|--|

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|        |    |
|--------|----|
| Result | NA |
|--------|----|

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

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

**Form: Exclusion Criteria (21)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:05**

**Generated On: 20 Jul 2016 16:57:04**

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

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|                     |   |                                  |
|---------------------|---|----------------------------------|
| Exclusion Criterion | For women only : Subject<br>does not agree to use an<br>acceptable method of<br>effective contraception | <input checked="" type="radio"/> |
|---------------------|---|----------------------------------|

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

---

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

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

**Form: Demographics**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:05**

**Generated On: 20 Jul 2016 16:57:04**

|  |  |
|--|--|
| Date of Birth                                | (b) (6)  |
| Sex  | Male <input checked="" type="radio"/>                      |
| Race   | Black or African American <input checked="" type="radio"/> |
| Other, specify                               |  |
| Ethnicity                                    | Not Hispanic <input checked="" type="radio"/>              |
| Date the Subject signed the Informed Consent | 25 FEB 2014<br>DD/MMM/YYYY                                 |
| Time the Subject signed the Informed Consent | 09:51<br>hour:min 24-hour clock                            |
| Age(Derived)                                 | 32   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

**Form: Medical History/Concomitant Disease**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:06**

**Generated On: 20 Jul 2016 16:57:04**

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Date of collection

25 FEB 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: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:06**

**Generated On: 20 Jul 2016 16:57:04**

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|                    |                            |
|--------------------|----------------------------|
| Date of collection | 25 FEB 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 | WISDOM TEETH REMOVED<br>TIMES 3 |
|-----------------------|---------------------------------|

---

|                           |             |
|---------------------------|-------------|
| Onset Date<br>DD/MMM/YYYY | UN UNK 2002 |
|---------------------------|-------------|

---

|                          |             |
|--------------------------|-------------|
| Stop Date<br>DD/MMM/YYYY | UN UNK 2002 |
|--------------------------|-------------|

---

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

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:06**

**Generated On: 20 Jul 2016 16:57:04**

---

|                    |                            |
|--------------------|----------------------------|
| Date of collection | 25 FEB 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 | BROKEN BONES RIGHT HAND,<br>CASTING |
|-----------------------|-------------------------------------|

---

|                           |             |
|---------------------------|-------------|
| Onset Date<br>DD/MMM/YYYY | UN UNK 2001 |
|---------------------------|-------------|

---

|                          |             |
|--------------------------|-------------|
| Stop Date<br>DD/MMM/YYYY | UN UNK 2001 |
|--------------------------|-------------|

---

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

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:06**

**Generated On: 20 Jul 2016 16:57:04**

---

Date of collection

25 FEB 2014  
DD/MMM/YYYY

---

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

Yes ☒

---

Number

3

---

Diagnosis Description

CONJUNCTIVAL INJECTION  
SINCE CHILDHOOD

---

Onset Date  
DD/MMM/YYYY

UN UNK 1988

---

Stop Date  
DD/MMM/YYYY

---

Ongoing?

True

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:10**

**Generated On: 20 Jul 2016 16:57:04**

---

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 25 FEB 2014  
DD/MMM/YYYY

---

Time of assessment 10:55  
hour:min 24-hour clock

---

Pulse rate 67  
beats per minute

---

Respiratory rate 16  
breaths per minute

---

Blood Pressure (systolic) 133  
mmHg

---

Blood Pressure (diastolic) 78  
mmHg

---

Vital Signs Position of Subject Supine ☒



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

**Form: Physical Examination**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:06**

**Generated On: 20 Jul 2016 16:57:04**

---

Was the physical examination performed?

Yes ☒

---

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

---

Date of assessment

25 FEB 2014  
DD/MMM/YYYY

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

**Form: Physical Examination (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:06**

**Generated On: 20 Jul 2016 16:57:04**

---

Was the physical examination performed? Yes ☒

---

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

---

Date of assessment 25 FEB 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: 1194**

**Folder: Screening**

**Form: Physical Examination (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:06**

**Generated On: 20 Jul 2016 16:57:04**

---

Was the physical examination performed?

Yes ☒

---

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

---

Date of assessment

25 FEB 2014  
DD/MMM/YYYY

---

System

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

---

Outcome

Abnormal ☒

---

Abnormal, please specify

CONJUNCTIVAL INJECTION

---

Clinically significant

No ☒

---

Not Done

False

---

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

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

**Form: Physical Examination (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:06**

**Generated On: 20 Jul 2016 16:57:04**

---

Was the physical examination performed? Yes ☒

---

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

---

Date of assessment 25 FEB 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: 1194**

**Folder: Screening**

**Form: Physical Examination (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:06**

**Generated On: 20 Jul 2016 16:57:04**

---

Was the physical examination performed? Yes ☒

---

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

---

Date of assessment 25 FEB 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: 1194**

**Folder: Screening**

**Form: Physical Examination (5)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:06**

**Generated On: 20 Jul 2016 16:57:04**

---

Was the physical examination performed? Yes ☒

---

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

---

Date of assessment 25 FEB 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: 1194**

**Folder: Screening**

**Form: Physical Examination (6)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:06**

**Generated On: 20 Jul 2016 16:57:04**

---

Was the physical examination performed? Yes ☒

---

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

---

Date of assessment 25 FEB 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: 1194**

**Folder: Screening**

**Form: Physical Examination (7)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:06**

**Generated On: 20 Jul 2016 16:57:04**

---

Was the physical examination performed? Yes ☒

---

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

---

Date of assessment 25 FEB 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: 1194**

**Folder: Screening**

**Form: Physical Examination (8)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:06**

**Generated On: 20 Jul 2016 16:57:04**

---

Was the physical examination performed? Yes ☒

---

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

---

Date of assessment 25 FEB 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: 1194**

**Folder: Screening**

**Form: Physical Examination (9)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:06**

**Generated On: 20 Jul 2016 16:57:04**

---

Was the physical examination performed? Yes ☒

---

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

---

Date of assessment 25 FEB 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: 1194**

**Folder: Screening**

**Form: Physical Examination (10)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:06**

**Generated On: 20 Jul 2016 16:57:04**

---

Was the physical examination performed? Yes ☒

---

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

---

Date of assessment 25 FEB 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: 1194**

**Folder: Screening**

**Form: Physical Examination (11)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:06**

**Generated On: 20 Jul 2016 16:57:04**

---

Was the physical examination performed?

Yes ☒

---

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

---

Date of assessment

25 FEB 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: 1194**

**Folder: Screening**

**Form: Physical Examination (12)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:06**

**Generated On: 20 Jul 2016 16:57:04**

---

Was the physical examination performed? Yes ☒

---

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

---

Date of assessment 25 FEB 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: 1194**

**Folder: Screening**

**Form: Physical Examination (13)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:06**

**Generated On: 20 Jul 2016 16:57:04**

---

Was the physical examination performed? Yes ☒

---

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

---

Date of assessment 25 FEB 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: 1194**

**Folder: Screening**

**Form: Physical Examination (14)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:06**

**Generated On: 20 Jul 2016 16:57:04**

---

Was the physical examination performed? Yes ☒

---

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

---

Date of assessment 25 FEB 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: 1194**

**Folder: Screening**

**Form: Physical Examination (15)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:06**

**Generated On: 20 Jul 2016 16:57:04**

---

Was the physical examination performed?

Yes ☒

---

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

---

Date of assessment

25 FEB 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: 1194**

**Folder: Screening**

**Form: Physical Examination (16)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:06**

**Generated On: 20 Jul 2016 16:57:04**

---

Was the physical examination performed?

Yes ☒

---

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

---

Date of assessment

25 FEB 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: 1194**

**Folder: Screening**

**Form: Physical Examination (17)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:06**

**Generated On: 20 Jul 2016 16:57:04**

---

Was the physical examination performed?

Yes ☒

---

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

---

Date of assessment

25 FEB 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: 1194**

**Folder: Screening**

**Form: Physical Examination (18)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:06**

**Generated On: 20 Jul 2016 16:57:04**

---

Was the physical examination performed?

Yes ☒

---

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

---

Date of assessment

25 FEB 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: 1194**

**Folder: Screening**

**Form: Physical Examination (19)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:06**

**Generated On: 20 Jul 2016 16:57:04**

---

Was the physical examination performed?

Yes ☒

---

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

---

Date of assessment

25 FEB 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: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:10**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Screening**

**Form: Identification of Current Cigarette Brand**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:10**

**Generated On: 20 Jul 2016 16:57:04**

---

|      |                            |
|------|----------------------------|
| Date | 25 FEB 2014<br>DD/MMM/YYYY |
|------|----------------------------|

---

|            |         |
|------------|---------|
| Brand name | NEWPORT |
|------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

**Form: THS 2.2 menthol product demonstration**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:10**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Screening**

**Form: Smoking History**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:10**

**Generated On: 20 Jul 2016 16:57:04**

---

Date of Assessment

25 FEB 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: 1194**

**Folder: Screening**

**Form: Weight and Height**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:10**

**Generated On: 20 Jul 2016 16:57:04**

---

Measurement(s) assessed?

Yes ☒

---

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

---

Date of assessment

25 FEB 2014  
DD/MMM/YYYY

---

Weight

76.2  
kg

---

Height

178  
cm

---

BMI (Derived)

24.0  
kg/m2

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:05**

**Generated On: 20 Jul 2016 16:57:04**

---

Was the ECG performed? Yes ☒

---

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

---

---

Date of assessment: 25 FEB 2014  
DD/MMM/YYYY

---

---

Position Supine ☒

---

---

Heart Rate 68  
beats per minute

---

---

QRS Interval 95  
msec

---

---

QT Interval 379  
msec

---

---

QTcB Interval 404  
msec

---

---

QTcF Interval 395  
msec

---

---

PR Interval 148  
msec

---

---

Interpretation Normal ☒

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:05**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Screening**

**Form: Spirometry (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:09**

**Generated On: 20 Jul 2016 16:57:04**

---

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 25 FEB 2014  
DD/MMM/YYYY

---

Time of assessment 11:20

---

Predicted FVC value 4.54  
L

---

Best measured FVC value 5.65  
L

---

Percent of predicted FVC value 125  
%

---

Best measured FEV1 value 3.69  
L

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

**Form: Spirometry (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:09**

**Generated On: 20 Jul 2016 16:57:04**

---

|                      |           |
|----------------------|-----------|
| Predicted FEV1 value | 3.78<br>L |
|----------------------|-----------|

---

|                                 |         |
|---------------------------------|---------|
| Percent of predicted FEV1 value | 98<br>% |
|---------------------------------|---------|

---

|                                   |      |
|-----------------------------------|------|
| Calculated ratio between FEV1/FVC | 0.65 |
|-----------------------------------|------|

---

|                 |             |
|-----------------|-------------|
| MEF 25/75 value | 1.86<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: 1194**

**Folder: Screening**

**Form: Spirometry (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:09**

**Generated On: 20 Jul 2016 16:57:04**

---

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 DD/MMM/YYYY 25 FEB 2014

---

Time of assessment 11:50

---

Name of bronchodilator ALBUTEROL SULFATE

---

Dose 180 MCG

---

Predicted FVC value 4.54 L

---

Best measured FVC value 5.53 L

---

Percent of predicted FVC value 122 %

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

**Form: Spirometry (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:09**

**Generated On: 20 Jul 2016 16:57:04**

---

|                          |           |
|--------------------------|-----------|
| Best measured FEV1 value | 3.68<br>L |
|--------------------------|-----------|

---

|                      |           |
|----------------------|-----------|
| Predicted FEV1 value | 3.78<br>L |
|----------------------|-----------|

---

|                                 |         |
|---------------------------------|---------|
| Percent of predicted FEV1 value | 97<br>% |
|---------------------------------|---------|

---

|                                   |      |
|-----------------------------------|------|
| Calculated ratio between FEV1/FVC | 0.67 |
|-----------------------------------|------|

---

|                 |             |
|-----------------|-------------|
| MEF 25/75 value | 1.88<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: 1194**

**Folder: Screening**

**Form: Chest X-Ray**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:11**

**Generated On: 20 Jul 2016 16:57:04**

---

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

Yes ☒

---

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

---

Date of assessment

05 MAR 2014  
DD/MMM/YYYY

---

System

Chest ☒

---

Interpretation

Normal ☒

---

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

---

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

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

**Form: Haematology**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:06**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Screening**

**Form: Clinical Chemistry**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:06**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Screening**

**Form: Urine analysis**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:06**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:06**

**Generated On: 20 Jul 2016 16:57:04**

---

Category

Serology ☒

---

Not Done

False

---

If Not Done, please specify the reason:

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Screening**

**Form: Urine Drug Screen**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:06**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

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

---

|                           |                            |
|---------------------------|----------------------------|
| Date of sample collection | 25 FEB 2014<br>DD/MMM/YYYY |
|---------------------------|----------------------------|

---

|                           |                                 |
|---------------------------|---------------------------------|
| Time of sample collection | 10:43<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: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:06**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

**Form: Alcohol Test**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:06**

**Generated On: 20 Jul 2016 16:57:04**

---

Was the alcohol test performed? Yes ☒

---

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

---

Method used Breath test ☒

---

Date of assessment 25 FEB 2014  
DD/MMM/YYYY

---

Time of assessment 10:47  
hour:min 24-hour clock

---

Result Negative ☒

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

**Form: Urine Cotinine Test**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:06**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

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

---

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

---

|                           |                            |
|---------------------------|----------------------------|
| Date of Sample Collection | 25 FEB 2014<br>DD/MMM/YYYY |
|---------------------------|----------------------------|

---

|                           |                                 |
|---------------------------|---------------------------------|
| Time of Sample Collection | 10:43<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: 1194**

**Folder: Screening**

**Form: Lab-BU-LabCorp CHEMISTRY(25 FEB 2014)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:11**

**Generated On: 20 Jul 2016 16:57:04**

---

Experiment Type

CHEMISTRY

---

Date of Sample Collection  
YYYY/MM/DD

25 FEB 2014

---

Please document clinically relevant abnormalities in the AE form

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

**Form: Lab-BU-LabCorp CHEMISTRY(25 FEB 2014)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:11**

**Generated On: 20 Jul 2016 16:57:04**

|   |                                       |
|---|---------------------------------------|
| Experiment Type                         | CHEMISTRY                             |
| Date of Sample Collection<br>YYYY/MM/DD | 25 FEB 2014                           |
| Subject Number                          |                                       |
| Date of Birth                           | (b) (6)                               |
| Gender                                  | Male <input checked="" type="radio"/> |
| Time of Sample Collection               | 11:28                                 |
| Analyte Name                            | GLUCOSE, SERUM                        |
| Code                                    | 001032                                |
| Result                                  | 91                                    |
| Unit                                    | MG/DL                                 |
| Lower limit                             | 65                                    |
| Upper limit                             | 99                                    |
| Flag                                    |                                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

**Form: Lab-BU-LabCorp CHEMISTRY(25 FEB 2014)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:11**

**Generated On: 20 Jul 2016 16:57:04**

---

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

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Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

05657100030

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:11**

**Generated On: 20 Jul 2016 16:57:04**

---

Experiment Type

CHEMISTRY

---

Date of Sample Collection  
YYYY/MM/DD

25 FEB 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Male ☒

---

Time of Sample Collection

11:28

---

Analyte Name

BUN

---

Code

001040

---

Result

12

---

Unit

MG/DL

---

Lower limit

6

---

Upper limit

20

---

Flag

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:11**

**Generated On: 20 Jul 2016 16:57:04**

---

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

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Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

05657100030

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:11**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

|   |             |
|---|-------------|
| Date of Sample Collection<br>YYYY/MM/DD | 25 FEB 2014 |
|---|-------------|

---

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

---

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

---

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

---

|                           |       |
|---------------------------|-------|
| Time of Sample Collection | 11:28 |
|---------------------------|-------|

---

|              |                    |
|--------------|--------------------|
| Analyte Name | CHOLESTEROL, TOTAL |
|--------------|--------------------|

---

|      |        |
|------|--------|
| Code | 001065 |
|------|--------|

---

|        |     |
|--------|-----|
| Result | 131 |
|--------|-----|

---

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

---

|             |     |
|-------------|-----|
| Lower limit | 100 |
|-------------|-----|

---

|             |     |
|-------------|-----|
| Upper limit | 199 |
|-------------|-----|

---

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

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:11**

**Generated On: 20 Jul 2016 16:57:04**

---

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

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Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

05657100030

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:11**

**Generated On: 20 Jul 2016 16:57:04**

|   |                                       |
|---|---------------------------------------|
| Experiment Type                         | CHEMISTRY                             |
| Date of Sample Collection<br>YYYY/MM/DD | 25 FEB 2014                           |
| Subject Number                          |                                       |
| Date of Birth                           | (b) (6)                               |
| Gender                                  | Male <input checked="" type="radio"/> |
| Time of Sample Collection               | 11:28                                 |
| Analyte Name                            | PROTEIN, TOTAL, SERUM                 |
| Code                                    | 001073                                |
| Result                                  | 7.3                                   |
| Unit                                    | G/DL                                  |
| Lower limit                             | 6.0                                   |
| Upper limit                             | 8.5                                   |
| Flag                                    |                                       |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:11**

**Generated On: 20 Jul 2016 16:57:04**

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

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Comment \_\_\_\_\_

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Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

05657100030

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:11**

**Generated On: 20 Jul 2016 16:57:04**

---

Experiment Type

CHEMISTRY

---

Date of Sample Collection  
YYYY/MM/DD

25 FEB 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Male ☒

---

Time of Sample Collection

11:28

---

Analyte Name

ALBUMIN, SERUM

---

Code

001081

---

Result

4.7

---

Unit

G/DL

---

Lower limit

3.5

---

Upper limit

5.5

---

Flag

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:11**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

05657100030

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:11**

**Generated On: 20 Jul 2016 16:57:04**

---

Experiment Type

CHEMISTRY

---

Date of Sample Collection  
YYYY/MM/DD

25 FEB 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Male ☒

---

Time of Sample Collection

11:28

---

Analyte Name

BILIRUBIN, TOTAL

---

Code

001099

---

Result

0.7

---

Unit

MG/DL

---

Lower limit

0.0

---

Upper limit

1.2

---

Flag

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:11**

**Generated On: 20 Jul 2016 16:57:04**

---

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

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Comment \_\_\_\_\_

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Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

05657100030

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:11**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

|   |             |
|---|-------------|
| Date of Sample Collection<br>YYYY/MM/DD | 25 FEB 2014 |
|---|-------------|

---

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

---

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

---

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

---

|                           |       |
|---------------------------|-------|
| Time of Sample Collection | 11:28 |
|---------------------------|-------|

---

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

---

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

---

|        |    |
|--------|----|
| Result | 67 |
|--------|----|

---

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

---

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

---

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

---

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

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:11**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

05657100030

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:11**

**Generated On: 20 Jul 2016 16:57:04**

|   |                                       |
|---|---------------------------------------|
| Experiment Type                         | CHEMISTRY                             |
| Date of Sample Collection<br>YYYY/MM/DD | 25 FEB 2014                           |
| Subject Number                          |                                       |
| Date of Birth                           | (b) (6)                               |
| Gender                                  | Male <input checked="" type="radio"/> |
| Time of Sample Collection               | 11:28                                 |
| Analyte Name                            | LDH                                   |
| Code                                    | 001115                                |
| Result                                  | 169                                   |
| Unit                                    | IU/L                                  |
| Lower limit                             | 0                                     |
| Upper limit                             | 225                                   |
| Flag                                    |                                       |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:11**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

05657100030

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:11**

**Generated On: 20 Jul 2016 16:57:04**

---

Experiment Type

CHEMISTRY

---

Date of Sample Collection  
YYYY/MM/DD

25 FEB 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Male ☒

---

Time of Sample Collection

11:28

---

Analyte Name

AST (SGOT)

---

Code

001123

---

Result

14

---

Unit

IU/L

---

Lower limit

0

---

Upper limit

40

---

Flag

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:11**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

05657100030

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:11**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

|   |             |
|---|-------------|
| Date of Sample Collection<br>YYYY/MM/DD | 25 FEB 2014 |
|---|-------------|

---

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

---

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

---

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

---

|                           |       |
|---------------------------|-------|
| Time of Sample Collection | 11:28 |
|---------------------------|-------|

---

|              |               |
|--------------|---------------|
| 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: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:11**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

Comment \_\_\_\_\_

---

Please document clinically relevant abnormalities in the AE form

---

Requisition or Accession number

05657100030

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:11**

**Generated On: 20 Jul 2016 16:57:04**

|   |                                       |
|---|---------------------------------------|
| Experiment Type                         | CHEMISTRY                             |
| Date of Sample Collection<br>YYYY/MM/DD | 25 FEB 2014                           |
| Subject Number                          |                                       |
| Date of Birth                           | (b) (6)                               |
| Gender                                  | Male <input checked="" type="radio"/> |
| Time of Sample Collection               | 11:28                                 |
| Analyte Name                            | POTASSIUM, SERUM                      |
| Code                                    | 001180                                |
| Result                                  | 4.7                                   |
| Unit                                    | MMOL/L                                |
| Lower limit                             | 3.5                                   |
| Upper limit                             | 5.2                                   |
| Flag                                    |                                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:11**

**Generated On: 20 Jul 2016 16:57:04**

---

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

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Comment \_\_\_\_\_

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Please document clinically relevant abnormalities in the AE form

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Requisition or Accession number

05657100030

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:11**

**Generated On: 20 Jul 2016 16:57:04**

|   |                                       |
|---|---------------------------------------|
| Experiment Type                         | CHEMISTRY                             |
| Date of Sample Collection<br>YYYY/MM/DD | 25 FEB 2014                           |
| Subject Number                          |                                       |
| Date of Birth                           | (b) (6)                               |
| Gender                                  | Male <input checked="" type="radio"/> |
| Time of Sample Collection               | 11:28                                 |
| 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: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:11**

**Generated On: 20 Jul 2016 16:57:04**

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

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Comment \_\_\_\_\_

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Please document clinically relevant abnormalities in the AE form

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Requisition or Accession number

05657100030

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:11**

**Generated On: 20 Jul 2016 16:57:04**

|   |                                       |
|---|---------------------------------------|
| Experiment Type                         | CHEMISTRY                             |
| Date of Sample Collection<br>YYYY/MM/DD | 25 FEB 2014                           |
| Subject Number                          |                                       |
| Date of Birth                           | (b) (6)                               |
| Gender                                  | Male <input checked="" type="radio"/> |
| Time of Sample Collection               | 11:28                                 |
| 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: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:11**

**Generated On: 20 Jul 2016 16:57:04**

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

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Comment \_\_\_\_\_

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Please document clinically relevant abnormalities in the AE form

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Requisition or Accession number

05657100030

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:11**

**Generated On: 20 Jul 2016 16:57:04**

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

---

|   |             |
|---|-------------|
| Date of Sample Collection<br>YYYY/MM/DD | 25 FEB 2014 |
|---|-------------|

---

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

---

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

---

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

---

|                           |       |
|---------------------------|-------|
| Time of Sample Collection | 11:28 |
|---------------------------|-------|

---

|              |                   |
|--------------|-------------------|
| Analyte Name | CREATININE, SERUM |
|--------------|-------------------|

---

|      |        |
|------|--------|
| Code | 001370 |
|------|--------|

---

|        |      |
|--------|------|
| Result | 1.07 |
|--------|------|

---

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

---

|             |      |
|-------------|------|
| Lower limit | 0.76 |
|-------------|------|

---

|             |      |
|-------------|------|
| Upper limit | 1.27 |
|-------------|------|

---

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

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:11**

**Generated On: 20 Jul 2016 16:57:04**

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

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Comment \_\_\_\_\_

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Please document clinically relevant abnormalities in the AE form

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Requisition or Accession number

05657100030

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:11**

**Generated On: 20 Jul 2016 16:57:04**

|   |                                       |
|---|---------------------------------------|
| Experiment Type                         | CHEMISTRY                             |
| Date of Sample Collection<br>YYYY/MM/DD | 25 FEB 2014                           |
| Subject Number                          |                                       |
| Date of Birth                           | (b) (6)                               |
| Gender                                  | Male <input checked="" type="radio"/> |
| Time of Sample Collection               | 11:28                                 |
| Analyte Name                            | ALT (SGPT)                            |
| Code                                    | 001545                                |
| Result                                  | 15                                    |
| Unit                                    | IU/L                                  |
| Lower limit                             | 0                                     |
| Upper limit                             | 44                                    |
| Flag                                    |                                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:11**

**Generated On: 20 Jul 2016 16:57:04**

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

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Comment \_\_\_\_\_

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Requisition or Accession number

05657100030

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:11**

**Generated On: 20 Jul 2016 16:57:04**

|   |                                       |
|---|---------------------------------------|
| Experiment Type                         | CHEMISTRY                             |
| Date of Sample Collection<br>YYYY/MM/DD | 25 FEB 2014                           |
| Subject Number                          |                                       |
| Date of Birth                           | (b) (6)                               |
| Gender                                  | Male <input checked="" type="radio"/> |
| Time of Sample Collection               | 11:28                                 |
| Analyte Name                            | GGT                                   |
| Code                                    | 001958                                |
| Result                                  | 21                                    |
| Unit                                    | IU/L                                  |
| Lower limit                             | 0                                     |
| Upper limit                             | 65                                    |
| Flag                                    |                                       |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:11**

**Generated On: 20 Jul 2016 16:57:04**

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

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Comment \_\_\_\_\_

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Requisition or Accession number

05657100030

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:11**

**Generated On: 20 Jul 2016 16:57:04**

|   |                                       |
|---|---------------------------------------|
| Experiment Type                         | CHEMISTRY                             |
| Date of Sample Collection<br>YYYY/MM/DD | 25 FEB 2014                           |
| Subject Number                          |                                       |
| Date of Birth                           | (b) (6)                               |
| Gender                                  | Male <input checked="" type="radio"/> |
| Time of Sample Collection               | 11:28                                 |
| 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: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:11**

**Generated On: 20 Jul 2016 16:57:04**

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

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Comment \_\_\_\_\_

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Requisition or Accession number

05657100030

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

**Form: Lab-BU-LabCorp SEROLOGY(25 FEB 2014)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:12**

**Generated On: 20 Jul 2016 16:57:04**

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Experiment Type

SEROLOGY

---

Date of Sample Collection  
YYYY/MM/DD

25 FEB 2014

---

Please document clinically relevant abnormalities in the AE form

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

**Form: Lab-BU-LabCorp SEROLOGY(25 FEB 2014)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:12**

**Generated On: 20 Jul 2016 16:57:04**

|   |                                       |
|---|---------------------------------------|
| Experiment Type                         | SEROLOGY                              |
| Date of Sample Collection<br>YYYY/MM/DD | 25 FEB 2014                           |
| Subject Number                          |                                       |
| Date of Birth                           | (b) (6)                               |
| Gender                                  | Male <input checked="" type="radio"/> |
| Time of Sample Collection               | 11:28                                 |
| 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: 1194**

**Folder: Screening**

**Form: Lab-BU-LabCorp SEROLOGY(25 FEB 2014)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:12**

**Generated On: 20 Jul 2016 16:57:04**

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

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Comment \_\_\_\_\_

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Please document clinically relevant abnormalities in the AE form

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Requisition or Accession number

05657100030

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:12**

**Generated On: 20 Jul 2016 16:57:04**

---

Experiment Type

SEROLOGY

---

Date of Sample Collection  
YYYY/MM/DD

25 FEB 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Male ☒

---

Time of Sample Collection

11:28

---

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: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:12**

**Generated On: 20 Jul 2016 16:57:04**

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

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Comment \_\_\_\_\_

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Requisition or Accession number

05657100030

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:12**

**Generated On: 20 Jul 2016 16:57:04**

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Experiment Type

SEROLOGY

---

Date of Sample Collection  
YYYY/MM/DD

25 FEB 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Male ☒

---

Time of Sample Collection

11:28

---

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: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:12**

**Generated On: 20 Jul 2016 16:57:04**

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

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Comment \_\_\_\_\_

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Requisition or Accession number

05657100030

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

**Form: Lab-BU-LabCorp HEMATOLOGY(25 FEB 2014)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:13**

**Generated On: 20 Jul 2016 16:57:04**

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Experiment Type

HEMATOLOGY

---

Date of Sample Collection  
YYYY/MM/DD

25 FEB 2014

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

**Form: Lab-BU-LabCorp HEMATOLOGY(25 FEB 2014)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:13**

**Generated On: 20 Jul 2016 16:57:04**

|   |                                       |
|---|---------------------------------------|
| Experiment Type                         | HEMATOLOGY                            |
| Date of Sample Collection<br>YYYY/MM/DD | 25 FEB 2014                           |
| Subject Number                          |                                       |
| Date of Birth                           | (b) (6)                               |
| Gender                                  | Male <input checked="" type="radio"/> |
| Time of Sample Collection               | 11:28                                 |
| Analyte Name                            | WBC                                   |
| Code                                    | 005025                                |
| Result                                  | 7.0                                   |
| Unit                                    | X10E3/UL                              |
| Lower limit                             | 3.4                                   |
| Upper limit                             | 10.8                                  |
| Flag                                    |                                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

**Form: Lab-BU-LabCorp HEMATOLOGY(25 FEB 2014)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:13**

**Generated On: 20 Jul 2016 16:57:04**

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

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Comment \_\_\_\_\_

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Requisition or Accession number

05657100030

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:13**

**Generated On: 20 Jul 2016 16:57:04**

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

---

|   |             |
|---|-------------|
| Date of Sample Collection<br>YYYY/MM/DD | 25 FEB 2014 |
|---|-------------|

---

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

---

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

---

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

---

|                           |       |
|---------------------------|-------|
| Time of Sample Collection | 11:28 |
|---------------------------|-------|

---

|              |     |
|--------------|-----|
| Analyte Name | RBC |
|--------------|-----|

---

|      |        |
|------|--------|
| Code | 005033 |
|------|--------|

---

|        |      |
|--------|------|
| Result | 4.95 |
|--------|------|

---

|      |          |
|------|----------|
| Unit | X10E6/UL |
|------|----------|

---

|             |      |
|-------------|------|
| Lower limit | 4.14 |
|-------------|------|

---

|             |      |
|-------------|------|
| Upper limit | 5.80 |
|-------------|------|

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

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:13**

**Generated On: 20 Jul 2016 16:57:04**

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

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Comment \_\_\_\_\_

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Requisition or Accession number

05657100030

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:13**

**Generated On: 20 Jul 2016 16:57:04**

|   |                                       |
|---|---------------------------------------|
| Experiment Type                         | HEMATOLOGY                            |
| Date of Sample Collection<br>YYYY/MM/DD | 25 FEB 2014                           |
| Subject Number                          |                                       |
| Date of Birth                           | (b) (6)                               |
| Gender                                  | Male <input checked="" type="radio"/> |
| Time of Sample Collection               | 11:28                                 |
| Analyte Name                            | HEMOGLOBIN                            |
| Code                                    | 005041                                |
| Result                                  | 15.7                                  |
| Unit                                    | G/DL                                  |
| Lower limit                             | 12.6                                  |
| Upper limit                             | 17.7                                  |
| Flag                                    |                                       |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:13**

**Generated On: 20 Jul 2016 16:57:04**

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

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Comment \_\_\_\_\_

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Requisition or Accession number

05657100030

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:13**

**Generated On: 20 Jul 2016 16:57:04**

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Experiment Type

HEMATOLOGY

---

Date of Sample Collection  
YYYY/MM/DD

25 FEB 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Male ☒

---

Time of Sample Collection

11:28

---

Analyte Name

HEMATOCRIT

---

Code

005058

---

Result

45.8

---

Unit

%

---

Lower limit

37.5

---

Upper limit

51.0

---

Flag

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:13**

**Generated On: 20 Jul 2016 16:57:04**

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

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Comment \_\_\_\_\_

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Requisition or Accession number

05657100030

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:13**

**Generated On: 20 Jul 2016 16:57:04**

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Experiment Type

HEMATOLOGY

---

Date of Sample Collection  
YYYY/MM/DD

25 FEB 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Male ☒

---

Time of Sample Collection

11:28

---

Analyte Name

MCV

---

Code

015065

---

Result

93

---

Unit

FL

---

Lower limit

79

---

Upper limit

97

---

Flag

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:13**

**Generated On: 20 Jul 2016 16:57:04**

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

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Comment \_\_\_\_\_

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Requisition or Accession number

05657100030

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:13**

**Generated On: 20 Jul 2016 16:57:04**

|   |                                       |
|---|---------------------------------------|
| Experiment Type                         | HEMATOLOGY                            |
| Date of Sample Collection<br>YYYY/MM/DD | 25 FEB 2014                           |
| Subject Number                          |                                       |
| Date of Birth                           | (b) (6)                               |
| Gender                                  | Male <input checked="" type="radio"/> |
| Time of Sample Collection               | 11:28                                 |
| Analyte Name                            | MCH                                   |
| Code                                    | 015073                                |
| Result                                  | 31.7                                  |
| Unit                                    | PG                                    |
| Lower limit                             | 26.6                                  |
| Upper limit                             | 33.0                                  |
| Flag                                    |                                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:13**

**Generated On: 20 Jul 2016 16:57:04**

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

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Comment \_\_\_\_\_

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Requisition or Accession number

05657100030

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:13**

**Generated On: 20 Jul 2016 16:57:04**

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

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|   |             |
|---|-------------|
| Date of Sample Collection<br>YYYY/MM/DD | 25 FEB 2014 |
|---|-------------|

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

---

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

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

---

|                           |       |
|---------------------------|-------|
| Time of Sample Collection | 11:28 |
|---------------------------|-------|

---

|              |      |
|--------------|------|
| Analyte Name | MCHC |
|--------------|------|

---

|      |        |
|------|--------|
| Code | 015081 |
|------|--------|

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|        |      |
|--------|------|
| Result | 34.3 |
|--------|------|

---

|      |      |
|------|------|
| Unit | G/DL |
|------|------|

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|             |      |
|-------------|------|
| Lower limit | 31.5 |
|-------------|------|

---

|             |      |
|-------------|------|
| Upper limit | 35.7 |
|-------------|------|

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

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:13**

**Generated On: 20 Jul 2016 16:57:04**

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

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Comment \_\_\_\_\_

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Please document clinically relevant abnormalities in the AE form

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Requisition or Accession number

05657100030

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:13**

**Generated On: 20 Jul 2016 16:57:04**

|   |                                       |
|---|---------------------------------------|
| Experiment Type                         | HEMATOLOGY                            |
| Date of Sample Collection<br>YYYY/MM/DD | 25 FEB 2014                           |
| Subject Number                          |                                       |
| Date of Birth                           | (b) (6)                               |
| Gender                                  | Male <input checked="" type="radio"/> |
| Time of Sample Collection               | 11:28                                 |
| Analyte Name                            | NEUTROPHILS                           |
| Code                                    | 015107                                |
| Result                                  | 38                                    |
| Unit                                    | %                                     |
| Lower limit                             | 40                                    |
| Upper limit                             | 74                                    |
| Flag                                    | Low <input checked="" type="radio"/>  |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:13**

**Generated On: 20 Jul 2016 16:57:04**

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Clinically Significant?

No ☒

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Comment

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Requisition or Accession number

05657100030

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:13**

**Generated On: 20 Jul 2016 16:57:04**

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

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|   |             |
|---|-------------|
| Date of Sample Collection<br>YYYY/MM/DD | 25 FEB 2014 |
|---|-------------|

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

---

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

---

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

---

|                           |       |
|---------------------------|-------|
| Time of Sample Collection | 11:28 |
|---------------------------|-------|

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|              |        |
|--------------|--------|
| Analyte Name | LYMPHS |
|--------------|--------|

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|      |        |
|------|--------|
| Code | 015123 |
|------|--------|

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|        |    |
|--------|----|
| Result | 47 |
|--------|----|

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|      |   |
|------|---|
| Unit | % |
|------|---|

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|             |    |
|-------------|----|
| Lower limit | 14 |
|-------------|----|

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|             |    |
|-------------|----|
| Upper limit | 46 |
|-------------|----|

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|      |                                       |
|------|---------------------------------------|
| Flag | High <input checked="" type="radio"/> |
|------|---------------------------------------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:13**

**Generated On: 20 Jul 2016 16:57:04**

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Clinically Significant?

No ☒

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Comment

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Please document clinically relevant abnormalities in the AE form

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Requisition or Accession number

05657100030

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:13**

**Generated On: 20 Jul 2016 16:57:04**

|   |                                       |
|---|---------------------------------------|
| Experiment Type                         | HEMATOLOGY                            |
| Date of Sample Collection<br>YYYY/MM/DD | 25 FEB 2014                           |
| Subject Number                          |                                       |
| Date of Birth                           | (b) (6)                               |
| Gender                                  | Male <input checked="" type="radio"/> |
| Time of Sample Collection               | 11:28                                 |
| Analyte Name                            | MONOCYTES                             |
| Code                                    | 015131                                |
| Result                                  | 11                                    |
| Unit                                    | %                                     |
| Lower limit                             | 4                                     |
| Upper limit                             | 12                                    |
| Flag                                    |                                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:13**

**Generated On: 20 Jul 2016 16:57:04**

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

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Comment \_\_\_\_\_

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Please document clinically relevant abnormalities in the AE form

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Requisition or Accession number

05657100030

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:13**

**Generated On: 20 Jul 2016 16:57:04**

|   |                                       |
|---|---------------------------------------|
| Experiment Type                         | HEMATOLOGY                            |
| Date of Sample Collection<br>YYYY/MM/DD | 25 FEB 2014                           |
| Subject Number                          |                                       |
| Date of Birth                           | (b) (6)                               |
| Gender                                  | Male <input checked="" type="radio"/> |
| Time of Sample Collection               | 11:28                                 |
| Analyte Name                            | EOS                                   |
| Code                                    | 015149                                |
| Result                                  | 4                                     |
| Unit                                    | %                                     |
| Lower limit                             | 0                                     |
| Upper limit                             | 5                                     |
| Flag                                    |                                       |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:13**

**Generated On: 20 Jul 2016 16:57:04**

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

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Comment \_\_\_\_\_

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Please document clinically relevant abnormalities in the AE form

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Requisition or Accession number

05657100030

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:13**

**Generated On: 20 Jul 2016 16:57:04**

|   |                                       |
|---|---------------------------------------|
| Experiment Type                         | HEMATOLOGY                            |
| Date of Sample Collection<br>YYYY/MM/DD | 25 FEB 2014                           |
| Subject Number                          |                                       |
| Date of Birth                           | (b) (6)                               |
| Gender                                  | Male <input checked="" type="radio"/> |
| Time of Sample Collection               | 11:28                                 |
| Analyte Name                            | BASOS                                 |
| Code                                    | 015156                                |
| Result                                  | 0                                     |
| Unit                                    | %                                     |
| Lower limit                             | 0                                     |
| Upper limit                             | 3                                     |
| Flag                                    |                                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:13**

**Generated On: 20 Jul 2016 16:57:04**

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

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Comment \_\_\_\_\_

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Please document clinically relevant abnormalities in the AE form

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Requisition or Accession number

05657100030

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:13**

**Generated On: 20 Jul 2016 16:57:04**

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Experiment Type

HEMATOLOGY

---

Date of Sample Collection  
YYYY/MM/DD

25 FEB 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Male ☒

---

Time of Sample Collection

11:28

---

Analyte Name

PLATELETS

---

Code

015172

---

Result

210

---

Unit

X10E3/UL

---

Lower limit

155

---

Upper limit

379

---

Flag

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:13**

**Generated On: 20 Jul 2016 16:57:04**

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

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Comment \_\_\_\_\_

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Please document clinically relevant abnormalities in the AE form

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Requisition or Accession number

05657100030

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:13**

**Generated On: 20 Jul 2016 16:57:04**

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

---

|   |             |
|---|-------------|
| Date of Sample Collection<br>YYYY/MM/DD | 25 FEB 2014 |
|---|-------------|

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

---

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

---

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

---

|                           |       |
|---------------------------|-------|
| Time of Sample Collection | 11:28 |
|---------------------------|-------|

---

|              |                        |
|--------------|------------------------|
| Analyte Name | NEUTROPHILS (ABSOLUTE) |
|--------------|------------------------|

---

|      |        |
|------|--------|
| Code | 015909 |
|------|--------|

---

|        |     |
|--------|-----|
| Result | 2.6 |
|--------|-----|

---

|      |          |
|------|----------|
| Unit | X10E3/UL |
|------|----------|

---

|             |     |
|-------------|-----|
| Lower limit | 1.4 |
|-------------|-----|

---

|             |     |
|-------------|-----|
| Upper limit | 7.0 |
|-------------|-----|

---

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

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:13**

**Generated On: 20 Jul 2016 16:57:04**

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

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Comment \_\_\_\_\_

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Please document clinically relevant abnormalities in the AE form

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Requisition or Accession number

05657100030

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:13**

**Generated On: 20 Jul 2016 16:57:04**

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

---

|   |             |
|---|-------------|
| Date of Sample Collection<br>YYYY/MM/DD | 25 FEB 2014 |
|---|-------------|

---

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

---

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

---

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

---

|                           |       |
|---------------------------|-------|
| Time of Sample Collection | 11:28 |
|---------------------------|-------|

---

|              |                   |
|--------------|-------------------|
| Analyte Name | LYMPHS (ABSOLUTE) |
|--------------|-------------------|

---

|      |        |
|------|--------|
| Code | 015917 |
|------|--------|

---

|        |     |
|--------|-----|
| Result | 3.3 |
|--------|-----|

---

|      |          |
|------|----------|
| Unit | X10E3/UL |
|------|----------|

---

|             |     |
|-------------|-----|
| Lower limit | 0.7 |
|-------------|-----|

---

|             |     |
|-------------|-----|
| Upper limit | 3.1 |
|-------------|-----|

---

|      |                                       |
|------|---------------------------------------|
| Flag | High <input checked="" type="radio"/> |
|------|---------------------------------------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:13**

**Generated On: 20 Jul 2016 16:57:04**

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Clinically Significant?

No ☒

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Comment

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Please document clinically relevant abnormalities in the AE form

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Requisition or Accession number

05657100030

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:13**

**Generated On: 20 Jul 2016 16:57:04**

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Experiment Type

HEMATOLOGY

---

Date of Sample Collection  
YYYY/MM/DD

25 FEB 2014

---

Subject Number

---

Date of Birth

(b) (6)

---

Gender

Male ☒

---

Time of Sample Collection

11:28

---

Analyte Name

MONOCYTES(ABSOLUTE)

---

Code

015925

---

Result

0.8

---

Unit

X10E3/UL

---

Lower limit

0.1

---

Upper limit

0.9

---

Flag

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:13**

**Generated On: 20 Jul 2016 16:57:04**

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

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Comment \_\_\_\_\_

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Requisition or Accession number

05657100030

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:13**

**Generated On: 20 Jul 2016 16:57:04**

|   |                                       |
|---|---------------------------------------|
| Experiment Type                         | HEMATOLOGY                            |
| Date of Sample Collection<br>YYYY/MM/DD | 25 FEB 2014                           |
| Subject Number                          |                                       |
| Date of Birth                           | (b) (6)                               |
| Gender                                  | Male <input checked="" type="radio"/> |
| Time of Sample Collection               | 11:28                                 |
| Analyte Name                            | EOS (ABSOLUTE)                        |
| Code                                    | 015933                                |
| Result                                  | 0.3                                   |
| Unit                                    | X10E3/UL                              |
| Lower limit                             | 0.0                                   |
| Upper limit                             | 0.4                                   |
| Flag                                    |                                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:13**

**Generated On: 20 Jul 2016 16:57:04**

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

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Comment \_\_\_\_\_

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Requisition or Accession number

05657100030

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

**Form: Lab-BU-LabCorp (18)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:13**

**Generated On: 20 Jul 2016 16:57:04**

|   |                                       |
|---|---------------------------------------|
| Experiment Type                         | HEMATOLOGY                            |
| Date of Sample Collection<br>YYYY/MM/DD | 25 FEB 2014                           |
| Subject Number                          |                                       |
| Date of Birth                           | (b) (6)                               |
| Gender                                  | Male <input checked="" type="radio"/> |
| Time of Sample Collection               | 11:28                                 |
| Analyte Name                            | BASO (ABSOLUTE)                       |
| Code                                    | 015941                                |
| Result                                  | 0.0                                   |
| Unit                                    | X10E3/UL                              |
| Lower limit                             | 0.0                                   |
| Upper limit                             | 0.2                                   |
| Flag                                    |                                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

**Form: Lab-BU-LabCorp (18)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:13**

**Generated On: 20 Jul 2016 16:57:04**

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

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Comment \_\_\_\_\_

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Requisition or Accession number

05657100030

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

**Form: Lab-BU-LabCorp URINALYSIS(25 FEB 2014)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:15**

**Generated On: 20 Jul 2016 16:57:04**

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Experiment Type

URINALYSIS

---

Date of Sample Collection  
YYYY/MM/DD

25 FEB 2014

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

**Form: Lab-BU-LabCorp URINALYSIS(25 FEB 2014)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:15**

**Generated On: 20 Jul 2016 16:57:04**

|   |                                       |
|---|---------------------------------------|
| Experiment Type                         | URINALYSIS                            |
| Date of Sample Collection<br>YYYY/MM/DD | 25 FEB 2014                           |
| Subject Number                          |                                       |
| Date of Birth                           | (b) (6)                               |
| Gender                                  | Male <input checked="" type="radio"/> |
| Time of Sample Collection               | 10:50                                 |
| Analyte Name                            | SPECIFIC GRAVITY                      |
| Code                                    | 13060                                 |
| Result                                  | 1.01                                  |
| Unit                                    |                                       |
| Lower limit                             | 1.001                                 |
| Upper limit                             | 1.035                                 |
| Flag                                    |                                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

**Form: Lab-BU-LabCorp URINALYSIS(25 FEB 2014)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:15**

**Generated On: 20 Jul 2016 16:57:04**

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

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Comment \_\_\_\_\_

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Requisition or Accession number \_\_\_\_\_

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:15**

**Generated On: 20 Jul 2016 16:57:04**

|   |                                       |
|---|---------------------------------------|
| Experiment Type                         | URINALYSIS                            |
| Date of Sample Collection<br>YYYY/MM/DD | 25 FEB 2014                           |
| Subject Number                          |                                       |
| Date of Birth                           | (b) (6)                               |
| Gender                                  | Male <input checked="" type="radio"/> |
| Time of Sample Collection               | 10:50                                 |
| Analyte Name                            | PH                                    |
| Code                                    | 13078                                 |
| Result                                  | 5                                     |
| Unit                                    |                                       |
| Lower limit                             | 5                                     |
| Upper limit                             | 8                                     |
| Flag                                    |                                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:15**

**Generated On: 20 Jul 2016 16:57:04**

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

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Comment \_\_\_\_\_

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Requisition or Accession number \_\_\_\_\_

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:15**

**Generated On: 20 Jul 2016 16:57:04**

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|                 |            |
|-----------------|------------|
| Experiment Type | URINALYSIS |
|-----------------|------------|

---

|   |             |
|---|-------------|
| Date of Sample Collection<br>YYYY/MM/DD | 25 FEB 2014 |
|---|-------------|

---

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

---

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

---

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

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|                           |       |
|---------------------------|-------|
| Time of Sample Collection | 10:50 |
|---------------------------|-------|

---

|              |         |
|--------------|---------|
| Analyte Name | GLUCOSE |
|--------------|---------|

---

|      |       |
|------|-------|
| Code | 13086 |
|------|-------|

---

|        |        |
|--------|--------|
| Result | NORMAL |
|--------|--------|

---

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

---

|             |        |
|-------------|--------|
| Lower limit | NORMAL |
|-------------|--------|

---

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

---

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

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:15**

**Generated On: 20 Jul 2016 16:57:04**

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

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Comment \_\_\_\_\_

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Requisition or Accession number \_\_\_\_\_

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:15**

**Generated On: 20 Jul 2016 16:57:04**

|   |                                       |
|---|---------------------------------------|
| Experiment Type                         | URINALYSIS                            |
| Date of Sample Collection<br>YYYY/MM/DD | 25 FEB 2014                           |
| Subject Number                          |                                       |
| Date of Birth                           | (b) (6)                               |
| Gender                                  | Male <input checked="" type="radio"/> |
| Time of Sample Collection               | 10:50                                 |
| Analyte Name                            | PROTEIN                               |
| Code                                    | 13094                                 |
| Result                                  | NEGATIVE                              |
| Unit                                    |                                       |
| Lower limit                             | NEGATIVE                              |
| Upper limit                             |                                       |
| Flag                                    |                                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:15**

**Generated On: 20 Jul 2016 16:57:04**

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

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Comment \_\_\_\_\_

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Please document clinically relevant abnormalities in the AE form

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Requisition or Accession number \_\_\_\_\_

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:15**

**Generated On: 20 Jul 2016 16:57:04**

|   |                                       |
|---|---------------------------------------|
| Experiment Type                         | URINALYSIS                            |
| Date of Sample Collection<br>YYYY/MM/DD | 25 FEB 2014                           |
| Subject Number                          |                                       |
| Date of Birth                           | (b) (6)                               |
| Gender                                  | Male <input checked="" type="radio"/> |
| Time of Sample Collection               | 10:50                                 |
| Analyte Name                            | OCCULT BLOOD                          |
| Code                                    | 13102                                 |
| Result                                  | TRACE                                 |
| Unit                                    |                                       |
| Lower limit                             | NEGATIVE                              |
| Upper limit                             |                                       |
| Flag                                    | High <input checked="" type="radio"/> |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:15**

**Generated On: 20 Jul 2016 16:57:04**

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Clinically Significant?

No ☒

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Comment

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Requisition or Accession number

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:15**

**Generated On: 20 Jul 2016 16:57:04**

|   |                                       |
|---|---------------------------------------|
| Experiment Type                         | URINALYSIS                            |
| Date of Sample Collection<br>YYYY/MM/DD | 25 FEB 2014                           |
| Subject Number                          |                                       |
| Date of Birth                           | (b) (6)                               |
| Gender                                  | Male <input checked="" type="radio"/> |
| Time of Sample Collection               | 10:50                                 |
| Analyte Name                            | BILIRUBIN                             |
| Code                                    | 13104                                 |
| Result                                  | NEGATIVE                              |
| Unit                                    |                                       |
| Lower limit                             | NEGATIVE                              |
| Upper limit                             |                                       |
| Flag                                    |                                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:15**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

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: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:15**

**Generated On: 20 Jul 2016 16:57:04**

---

|                 |            |
|-----------------|------------|
| Experiment Type | URINALYSIS |
|-----------------|------------|

---

|   |             |
|---|-------------|
| Date of Sample Collection<br>YYYY/MM/DD | 25 FEB 2014 |
|---|-------------|

---

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

---

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

---

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

---

|                           |       |
|---------------------------|-------|
| Time of Sample Collection | 10:50 |
|---------------------------|-------|

---

|              |                |
|--------------|----------------|
| Analyte Name | NITRITE, URINE |
|--------------|----------------|

---

|      |       |
|------|-------|
| Code | 13106 |
|------|-------|

---

|        |          |
|--------|----------|
| Result | NEGATIVE |
|--------|----------|

---

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

---

|             |          |
|-------------|----------|
| Lower limit | NEGATIVE |
|-------------|----------|

---

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

---

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

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Screening**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:15**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

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: 1194**

**Folder: Screening**

**Form: FTND Questionnaire**

**Generated On: 20 Jul 2016 16:57:04**

---

|      |      |
|------|------|
| Type | FTND |
|------|------|

---

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

---

|                    |             |
|--------------------|-------------|
| Date of assessment | 2014 FEB 25 |
| DD/MMM/YYYY        | DD/MMM/YYYY |

---

|                    |                        |
|--------------------|------------------------|
| Time of assessment | 12:03                  |
|                    | 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? | 31-60 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? | Any other <input checked="" type="radio"/> |
|--|--|

---

|  |   |
|--|---|
| 4. How many cigarettes per day do you smoke? | 10 or less <input checked="" type="radio"/> |
|--|---|

---

|   |                                     |
|---|-------------------------------------|
| 5. Do you smoke more frequently during the first hours after awakening than during the rest of the day? | No <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: 1194**

**Folder: Screening**

**Form: Prochaska "Stage of Change" Questionnaire: Intention to Quit  
Smoking**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:10**

**Generated On: 20 Jul 2016 16:57:04**

---

Was paper questionnaire used? Yes ☒

---

Reason not done \_\_\_\_\_

---

Type PROCHASKA STAGE OF  
CHANGE QUESTIONNAIRE:  
INTENTION TO QUIT  
SMOKING

---

Date of assessment 25 FEB 2014  
DD/MMM/YYYY

---

Time of assessment 10:00  
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? 10

---

3. Are you seriously thinking of quitting smoking? No, not thinking of quitting ☒



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Admission (Day -2)**

**Form: Date of Visit**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:19**

**Generated On: 20 Jul 2016 16:57:04**

---

Date of Visit

06 MAR 2014  
DD/MMM/YYYY

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Admission (Day -2)**

**Form: Inclusion Criteria**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:17**

**Generated On: 20 Jul 2016 16:57:04**

---

\*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: 1194**

**Folder: Admission (Day -2)**

**Form: Inclusion Criteria (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:17**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Admission (Day -2)**

**Form: Inclusion Criteria (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:17**

**Generated On: 20 Jul 2016 16:57:04**

---

|                            |   |
|----------------------------|---|
| 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: 1194**

**Folder: Admission (Day -2)**

**Form: Inclusion Criteria (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:17**

**Generated On: 20 Jul 2016 16:57:04**

---

|                            |   |
|----------------------------|---|
| 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: 1194**

**Folder: Admission (Day -2)**

**Form: Inclusion Criteria (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:17**

**Generated On: 20 Jul 2016 16:57:04**

---

|                            |   |
|----------------------------|---|
| 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: 1194**

**Folder: Admission (Day -2)**

**Form: Exclusion Criteria**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:16**

**Generated On: 20 Jul 2016 16:57:04**

---

\*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: 1194**

**Folder: Admission (Day -2)**

**Form: Exclusion Criteria (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:16**

**Generated On: 20 Jul 2016 16:57:04**

---

|                            |   |
|----------------------------|---|
| 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: 1194**

**Folder: Admission (Day -2)**

**Form: Exclusion Criteria (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:16**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Admission (Day -2)**

**Form: Exclusion Criteria (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:16**

**Generated On: 20 Jul 2016 16:57:04**

---

|                            |   |
|----------------------------|---|
| 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: 1194**

**Folder: Admission (Day -2)**

**Form: Exclusion Criteria (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:16**

**Generated On: 20 Jul 2016 16:57:04**

---

|                            |   |
|----------------------------|---|
| 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: 1194**

**Folder: Admission (Day -2)**

**Form: Exclusion Criteria (5)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:16**

**Generated On: 20 Jul 2016 16:57:04**

---

|                            |   |
|----------------------------|---|
| 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: 1194**

**Folder: Admission (Day -2)**

**Form: Exclusion Criteria (6)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:16**

**Generated On: 20 Jul 2016 16:57:04**

---

|                            |    |
|----------------------------|----|
| 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: 1194**

**Folder: Admission (Day -2)**

**Form: Exclusion Criteria (7)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:16**

**Generated On: 20 Jul 2016 16:57:04**

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|                            |    |
|----------------------------|----|
| 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: 1194**

**Folder: Admission (Day -2)**

**Form: Exclusion Criteria (8)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:16**

**Generated On: 20 Jul 2016 16:57:04**

---

|                            |    |
|----------------------------|----|
| 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: 1194**

**Folder: Admission (Day -2)**

**Form: Exclusion Criteria (9)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:16**

**Generated On: 20 Jul 2016 16:57:04**

---

|                            |    |
|----------------------------|----|
| 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: 1194**

**Folder: Admission (Day -2)**

**Form: Exclusion Criteria (10)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:16**

**Generated On: 20 Jul 2016 16:57:04**

---

|                            |    |
|----------------------------|----|
| 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 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: 1194**

**Folder: Admission (Day -2)**

**Form: Exclusion Criteria (11)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:16**

**Generated On: 20 Jul 2016 16:57:04**

---

|                            |    |
|----------------------------|----|
| 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: 1194**

**Folder: Admission (Day -2)**

**Form: Exclusion Criteria (12)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:16**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

|                     |  |
|---------------------|--|
| Exclusion Criterion | Donation or receipt of whole blood or blood products within 3 months prior to Admission. |
|---------------------|--|

---

|        |    |
|--------|----|
| 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: 1194**

**Folder: Admission (Day -2)**

**Form: Exclusion Criteria (13)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:16**

**Generated On: 20 Jul 2016 16:57:04**

---

|                            |    |
|----------------------------|----|
| 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 | NA |
|--------|----|

---

\*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: 1194**

**Folder: Admission (Day -2)**

**Form: Exclusion Criteria (14)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:16**

**Generated On: 20 Jul 2016 16:57:04**

---

|                            |    |
|----------------------------|----|
| 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 | NA |
|--------|----|

---

\*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: 1194**

**Folder: Admission (Day -2)**

**Form: Vital Signs**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:19**

**Generated On: 20 Jul 2016 16:57:04**

---

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 13:23  
hour:min 24-hour clock

---

Pulse rate 51  
beats per minute

---

Respiratory rate 16  
breaths per minute

---

Blood Pressure (systolic) 130  
mmHg

---

Blood Pressure (diastolic) 76  
mmHg

---

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Admission (Day -2)**

**Form: Product preference**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:18**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Admission (Day -2)**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:34:18**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Admission (Day -2)**

**Form: Physical Examination**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:17**

**Generated On: 20 Jul 2016 16:57:04**

---

Was the physical examination performed?

Yes ☒

---

If No, please specify the reason:

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Admission (Day -2)**

**Form: Physical Examination (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:17**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Admission (Day -2)**

**Form: Physical Examination (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:17**

**Generated On: 20 Jul 2016 16:57:04**

---

Was the physical examination performed? Yes ☒

---

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

---

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

---

Outcome Abnormal ☒

---

Abnormal, please specify CONJUNCTIVAL INJECTION

---

Clinically significant No ☒

---

Not Done False

---

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

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Admission (Day -2)**

**Form: Physical Examination (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:17**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Admission (Day -2)**

**Form: Physical Examination (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:17**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Admission (Day -2)**

**Form: Physical Examination (5)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:17**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Admission (Day -2)**

**Form: Physical Examination (6)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:17**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Admission (Day -2)**

**Form: Physical Examination (7)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:17**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Admission (Day -2)**

**Form: Physical Examination (8)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:17**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Admission (Day -2)**

**Form: Physical Examination (9)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:17**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Admission (Day -2)**

**Form: Physical Examination (10)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:17**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Admission (Day -2)**

**Form: Physical Examination (11)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:17**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Admission (Day -2)**

**Form: Physical Examination (12)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:17**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Admission (Day -2)**

**Form: Physical Examination (13)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:17**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Admission (Day -2)**

**Form: Physical Examination (14)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:17**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Admission (Day -2)**

**Form: Physical Examination (15)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:17**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Admission (Day -2)**

**Form: Physical Examination (16)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:17**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Admission (Day -2)**

**Form: Physical Examination (17)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:17**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Admission (Day -2)**

**Form: Physical Examination (18)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:17**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Admission (Day -2)**

**Form: Physical Examination (19)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:17**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Admission (Day -2)**

**Form: Identification of Current Cigarette Brand**

**Data signed: (hcoleman1) 18 Jun 2015 20:59:09**

**Generated On: 20 Jul 2016 16:57:04**

---

Brand name

NEWPORT GREEN

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Admission (Day -2)**

**Form: THS 2.2 menthol product test**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:18**

**Generated On: 20 Jul 2016 16:57:04**

---

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?

1

---

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: 1194**

**Folder: Admission (Day -2)**

**Form: Smoking History**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:18**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Admission (Day -2)**

**Form: Weight**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:19**

**Generated On: 20 Jul 2016 16:57:04**

---

Measurement(s) assessed?

Yes ☒

---

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

---

Time of assessment

13:00  
hour:min 24-hour clock

---

Weight

78.8  
kg

---

Waist circumference

84  
cm

---

BMI

24.9

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Admission (Day -2)**

**Form: Urine Drug Screen**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:17**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

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

---

|                           |                                 |
|---------------------------|---------------------------------|
| Time of sample collection | 12:59<br>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: 1194**

**Folder: Admission (Day -2)**

**Form: Urine Drug Screen (6)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:17**

**Generated On: 20 Jul 2016 16:57:04**

---

| Drug type | Result   |
|-----------|----------|
| Opiates   | Negative |

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Admission (Day -2)**

**Form: Alcohol Test**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:17**

**Generated On: 20 Jul 2016 16:57:04**

---

Was the alcohol test performed? Yes ☒

---

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

---

Method used Breath test ☒

---

Time of assessment 12:37  
hour:min 24-hour clock

---

Result Negative ☒

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Admission (Day -2)**

**Form: CO Breath Test**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:16**

**Generated On: 20 Jul 2016 16:57:04**

---

|                     |       |
|---------------------|-------|
| Assessment not done | False |
|---------------------|-------|

---

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

---

|                           |                        |
|---------------------------|------------------------|
| Actual Time of Assessment | 13:05                  |
|                           | hour:min 24-hour clock |

---

|        |     |
|--------|-----|
| Result | 22  |
|        | ppm |

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Admission (Day -2)**

**Form: Prochaska "Stage of Change" Questionnaire: Intention to Quit  
Smoking**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:18**

**Generated On: 20 Jul 2016 16:57:04**

---

Was paper questionnaire used? Yes ☒

---

Reason not done \_\_\_\_\_

---

Type PROCHASKA STAGE OF  
CHANGE QUESTIONNAIRE:  
INTENTION TO QUIT  
SMOKING

---

Date of assessment 06 MAR 2014  
DD/MMM/YYYY

---

Time of assessment \_\_\_\_\_

---

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? 10

---

3. Are you seriously thinking of quitting smoking? No, not thinking of quitting ☒

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Date of Visit**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:20**

**Generated On: 20 Jul 2016 16:57:04**

---

Date of Visit

07 MAR 2014  
DD/MMM/YYYY

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Vital Signs**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:20**

**Generated On: 20 Jul 2016 16:57:04**

---

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 09:33  
hour:min 24-hour clock

---

Pulse rate 59  
beats per minute

---

Respiratory rate 16  
breaths per minute

---

Blood Pressure (systolic) 139  
mmHg

---

Blood Pressure (diastolic) 81  
mmHg

---

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: CoHb Blood Sample**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:19**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

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

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 07 MAR 2014 |
|---------------------|-------------|

---

|           |  |
|-----------|--|
| Timepoint | 20:00 - 21:30 <input checked="" type="radio"/> |
|-----------|--|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 20:16 |
|--------------------------------|-------|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: CO Breath Test (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:19**

**Generated On: 20 Jul 2016 16:57:04**

---

|                     |       |
|---------------------|-------|
| 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 | 06:47 |
|---|-------|

---

|             |    |
|-------------|----|
| Result(ppm) | 10 |
|-------------|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: CO Breath Test (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:19**

**Generated On: 20 Jul 2016 16:57:04**

---

|                     |       |
|---------------------|-------|
| 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 | 12:06 |
|---|-------|

---

|             |    |
|-------------|----|
| Result(ppm) | 17 |
|-------------|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: CO Breath Test (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:19**

**Generated On: 20 Jul 2016 16:57:04**

---

|                     |       |
|---------------------|-------|
| 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 | 16:06 |
|---|-------|

---

|             |    |
|-------------|----|
| Result(ppm) | 17 |
|-------------|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: CO Breath Test (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:19**

**Generated On: 20 Jul 2016 16:57:04**

---

|                     |       |
|---------------------|-------|
| 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 | 20:11 |
|---|-------|

---

|             |    |
|-------------|----|
| Result(ppm) | 18 |
|-------------|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: 4 hour urine collection**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:20**

**Generated On: 20 Jul 2016 16:57:04**

---

|            |                        |
|------------|------------------------|
| Start Time | 10:08                  |
|            | hour:min 24-hour clock |

---

|          |                        |
|----------|------------------------|
| End Time | 14:08                  |
|          | hour:min 24-hour clock |

---

|        |     |
|--------|-----|
| Volume | 691 |
|        | mL  |

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Sample Urine Collection (4 Hour collection)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:20**

**Generated On: 20 Jul 2016 16:57:04**

---

Were samples for 4h collected? Yes ☒

---

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

---

How many primary tubes were collected? 13

---

How many back up tubes were collected? 13

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Lab\_BU\_COHB (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:21**

**Generated On: 20 Jul 2016 16:57:04**

|                               |                    |
|-------------------------------|--------------------|
| Sample Barcode                | 05115150001265     |
| Analyte                       | CARBOXYHEMOGLOBIN  |
| Sample type                   | BLOOD              |
| Result                        | 5.10               |
| Result Unit                   | %                  |
| Lab Status                    | OK                 |
| Sample comment                | .                  |
| 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-MAR-07        |
| Timepoint-minutes             |                    |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Lab\_BU\_COHB (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:21**

**Generated On: 20 Jul 2016 16:57:04**

---

Start Day (24 hour urine only) \_\_\_\_\_

---

End Day (24 hour Urine Only) \_\_\_\_\_

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:20**

**Generated On: 20 Jul 2016 16:57:04**

|  |                                 |
|--|---------------------------------|
| Date of Birth  | (b) (6)                         |
| Date of assessment<br>DD/MMM/YYYY                        | 2014 MAR 07<br>DD/MMM/YYYY      |
| Time of assessment                                       | 20:04<br>hour:min 24-hour clock |
| Assessment Status  | Completed                       |
| 1. Was smoking satisfying?                               | A lot                           |
| 2. Did cigarettes taste good?                            | Very little                     |
| 3. Did you enjoy the sensation in your throat and chest? | A lot                           |
| 4. Did smoking calm you down?                            | A lot                           |
| 5. Did smoking make you feel more awake?                 | Very little                     |
| 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?              | Very little                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:20**

**Generated On: 20 Jul 2016 16:57:04**

---

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? Quite a lot ☐

---

12. Did you enjoy smoking? Very little ☐

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Behavioral Risk Factor Surveillance System Questionnaire**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:19**

**Generated On: 20 Jul 2016 16:57:04**

---

|      |  |
|------|--|
| Type | BEHAVIORAL RISK FACTOR<br>SURVEILLANCE SYSTEM<br>QUESTIONNAIRE |
|------|--|

---

|                               |                           |
|-------------------------------|---------------------------|
| Was paper questionnaire used? | Yes <input type="radio"/> |
|-------------------------------|---------------------------|

---

|                 |  |
|-----------------|--|
| Reason not done |  |
|-----------------|--|

---

|                    |                            |
|--------------------|----------------------------|
| Date of assessment | 07 MAR 2014<br>DD/MMM/YYYY |
|--------------------|----------------------------|

---

|                    |                                 |
|--------------------|---------------------------------|
| Time of assessment | 21:27<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? | Yes <input type="radio"/> |
|--|---------------------------|

---

|  |  |
|--|--|
| How long has it been since you last smoked a cigarette, even one or two puffs? | Within the past month<br>(less than 1 month ago) <input type="radio"/> |
|--|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Behavioral Risk Factor Surveillance System Questionnaire**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:19**

**Generated On: 20 Jul 2016 16:57:04**

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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: 1194**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:19**

**Generated On: 20 Jul 2016 16:57:04**

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|      |                       |
|------|-----------------------|
| Type | SMOKING QUESTIONNAIRE |
|------|-----------------------|

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|                               |                           |
|-------------------------------|---------------------------|
| Was paper questionnaire used? | Yes <input type="radio"/> |
|-------------------------------|---------------------------|

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|                 |  |
|-----------------|--|
| Reason not done |  |
|-----------------|--|

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|                    |                            |
|--------------------|----------------------------|
| Date of assessment | 07 MAR 2014<br>DD/MMM/YYYY |
|--------------------|----------------------------|

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|                    |                                 |
|--------------------|---------------------------------|
| Time of assessment | 21:30<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? | 18 Years |
|---|----------|

---

|   |  |
|---|--|
| 5. If you are an ex-smoker of cigarettes: For how long have you quit now? |  |
|---|--|

---

|       |          |
|-------|----------|
| Years | 00 Years |
|-------|----------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:19**

**Generated On: 20 Jul 2016 16:57:04**

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|        |           |
|--------|-----------|
| Months | 04 Months |
|--------|-----------|

---

|      |         |
|------|---------|
| Days | 00 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 | 00 Years |
|-------|----------|

---

|        |           |
|--------|-----------|
| Months | 04 Months |
|--------|-----------|

---

|      |         |
|------|---------|
| Days | 00 Days |
|------|---------|

---

7. What brand of cigarettes/hand-rolled tobacco did you **NEWPORT**  
predominantly smoke in the last 12 months of smoking?

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:19**

**Generated On: 20 Jul 2016 16:57:04**

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|      |                       |
|------|-----------------------|
| Type | SMOKING QUESTIONNAIRE |
|------|-----------------------|

---

|                               |                           |
|-------------------------------|---------------------------|
| Was paper questionnaire used? | Yes <input type="radio"/> |
|-------------------------------|---------------------------|

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|                 |  |
|-----------------|--|
| Reason not done |  |
|-----------------|--|

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|                    |                            |
|--------------------|----------------------------|
| Date of assessment | 07 MAR 2014<br>DD/MMM/YYYY |
|--------------------|----------------------------|

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|                    |                                 |
|--------------------|---------------------------------|
| Time of assessment | 21:30<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? | 18 Years |
|---|----------|

---

|   |  |
|---|--|
| 5. If you are an ex-smoker of cigarettes: For how long have you quit now? |  |
|---|--|

---

|       |          |
|-------|----------|
| Years | 00 Years |
|-------|----------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:19**

**Generated On: 20 Jul 2016 16:57:04**

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|        |           |
|--------|-----------|
| Months | 04 Months |
|--------|-----------|

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|      |         |
|------|---------|
| Days | 00 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 | 00 Years |
|-------|----------|

---

|        |           |
|--------|-----------|
| Months | 04 Months |
|--------|-----------|

---

|      |         |
|------|---------|
| Days | 00 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) <input checked="" type="radio"/> |
|------|--|

---

8. On average, how many Manufactured cigarettes do/did you smoke per day?

---

|                                 |    |
|---------------------------------|----|
| Manufactured Cigarettes per day | 13 |
|---------------------------------|----|

---

8. On average, how many Hand-rolled Cigarettes do/did you smoke per day?

---

|                                |                                       |
|--------------------------------|---------------------------------------|
| Hand-rolled Cigarettes per day | None <input checked="" type="radio"/> |
|--------------------------------|---------------------------------------|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:19**

**Generated On: 20 Jul 2016 16:57:04**

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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: 1194**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:19**

**Generated On: 20 Jul 2016 16:57:04**

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|      |                       |
|------|-----------------------|
| Type | SMOKING QUESTIONNAIRE |
|------|-----------------------|

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|                               |                           |
|-------------------------------|---------------------------|
| Was paper questionnaire used? | Yes <input type="radio"/> |
|-------------------------------|---------------------------|

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|                 |  |
|-----------------|--|
| Reason not done |  |
|-----------------|--|

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|                    |                            |
|--------------------|----------------------------|
| Date of assessment | 07 MAR 2014<br>DD/MMM/YYYY |
|--------------------|----------------------------|

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|                    |                                 |
|--------------------|---------------------------------|
| Time of assessment | 21:30<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? | 18 Years |
|---|----------|

---

|   |  |
|---|--|
| 5. If you are an ex-smoker of cigarettes: For how long have you quit now? |  |
|---|--|

---

|       |          |
|-------|----------|
| Years | 00 Years |
|-------|----------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:19**

**Generated On: 20 Jul 2016 16:57:04**

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|        |           |
|--------|-----------|
| Months | 04 Months |
|--------|-----------|

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|      |         |
|------|---------|
| Days | 00 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 | 00 Years |
|-------|----------|

---

|        |           |
|--------|-----------|
| Months | 04 Months |
|--------|-----------|

---

|      |         |
|------|---------|
| Days | 00 Days |
|------|---------|

---

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking?

---

|      |   |
|------|---|
| Time | 1 year ago <input checked="" type="radio"/> |
|------|---|

---

8. On average, how many Manufactured cigarettes do/did you smoke per day?

---

|                                 |    |
|---------------------------------|----|
| Manufactured Cigarettes per day | 13 |
|---------------------------------|----|

---

|  |                                       |
|--|---------------------------------------|
| 8. On average, how many Hand-rolled Cigarettes do/did you smoke per day? | None <input checked="" type="radio"/> |
|--|---------------------------------------|

---

|                                |  |
|--------------------------------|--|
| Hand-rolled Cigarettes per day |  |
|--------------------------------|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:19**

**Generated On: 20 Jul 2016 16:57:04**

---

8. On average, how many cigars do/did you smoke per  
day? \_\_\_\_\_

---

Cigars \_\_\_\_\_ 05  
per day

---

8. On average, how many pipes do/did you smoke per  
day? \_\_\_\_\_

None ☒

---

Pipes \_\_\_\_\_  
per day

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:19**

**Generated On: 20 Jul 2016 16:57:04**

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|      |                       |
|------|-----------------------|
| Type | SMOKING QUESTIONNAIRE |
|------|-----------------------|

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|                               |                           |
|-------------------------------|---------------------------|
| Was paper questionnaire used? | Yes <input type="radio"/> |
|-------------------------------|---------------------------|

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|                 |  |
|-----------------|--|
| Reason not done |  |
|-----------------|--|

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|                    |                            |
|--------------------|----------------------------|
| Date of assessment | 07 MAR 2014<br>DD/MMM/YYYY |
|--------------------|----------------------------|

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|                    |                                 |
|--------------------|---------------------------------|
| Time of assessment | 21:30<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? | 18 Years |
|---|----------|

---

|   |  |
|---|--|
| 5. If you are an ex-smoker of cigarettes: For how long have you quit now? |  |
|---|--|

---

|       |          |
|-------|----------|
| Years | 00 Years |
|-------|----------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:19**

**Generated On: 20 Jul 2016 16:57:04**

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|        |           |
|--------|-----------|
| Months | 04 Months |
|--------|-----------|

---

|      |         |
|------|---------|
| Days | 00 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 | 00 Years |
|-------|----------|

---

|        |           |
|--------|-----------|
| Months | 04 Months |
|--------|-----------|

---

|      |         |
|------|---------|
| Days | 00 Days |
|------|---------|

---

7. What brand of cigarettes/hand-rolled tobacco did you **NEWPORT**  
predominantly smoke in the last 12 months of smoking?

---

|      |  |
|------|--|
| Time | 5 years ago <input checked="" type="radio"/> |
|------|--|

---

8. On average, how many Manufactured cigarettes  
do/did you smoke per day?

---

|                                    |    |
|------------------------------------|----|
| Manufactured Cigarettes<br>per day | 13 |
|------------------------------------|----|

---

|   |                                       |
|---|---------------------------------------|
| 8. On average, how many Hand-rolled Cigarettes do/did<br>you smoke per day? | None <input checked="" type="radio"/> |
|---|---------------------------------------|

---

|                                   |  |
|-----------------------------------|--|
| Hand-rolled Cigarettes<br>per day |  |
|-----------------------------------|--|

---

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:19**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:19**

**Generated On: 20 Jul 2016 16:57:04**

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|      |                       |
|------|-----------------------|
| Type | SMOKING QUESTIONNAIRE |
|------|-----------------------|

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|                               |                           |
|-------------------------------|---------------------------|
| Was paper questionnaire used? | Yes <input type="radio"/> |
|-------------------------------|---------------------------|

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|                 |  |
|-----------------|--|
| Reason not done |  |
|-----------------|--|

---

|                    |                            |
|--------------------|----------------------------|
| Date of assessment | 07 MAR 2014<br>DD/MMM/YYYY |
|--------------------|----------------------------|

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|                    |                                 |
|--------------------|---------------------------------|
| Time of assessment | 21:30<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? | 18 Years |
|---|----------|

---

|   |  |
|---|--|
| 5. If you are an ex-smoker of cigarettes: For how long have you quit now? |  |
|---|--|

---

|       |          |
|-------|----------|
| Years | 00 Years |
|-------|----------|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:19**

**Generated On: 20 Jul 2016 16:57:04**

---

|        |           |
|--------|-----------|
| Months | 04 Months |
|--------|-----------|

---

|      |         |
|------|---------|
| Days | 00 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 | 00 Years |
|-------|----------|

---

|        |           |
|--------|-----------|
| Months | 04 Months |
|--------|-----------|

---

|      |         |
|------|---------|
| Days | 00 Days |
|------|---------|

---

7. What brand of cigarettes/hand-rolled tobacco did you **NEWPORT**  
predominantly smoke in the last 12 months of smoking?

---

|      |   |
|------|---|
| Time | 10 years ago <input checked="" type="radio"/> |
|------|---|

---

8. On average, how many Manufactured cigarettes  
do/did you smoke per day?

---

|                                    |    |
|------------------------------------|----|
| Manufactured Cigarettes<br>per day | 13 |
|------------------------------------|----|

---

|   |                                       |
|---|---------------------------------------|
| 8. On average, how many Hand-rolled Cigarettes do/did<br>you smoke per day? | None <input checked="" type="radio"/> |
|---|---------------------------------------|

---

|                                   |  |
|-----------------------------------|--|
| Hand-rolled Cigarettes<br>per day |  |
|-----------------------------------|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:19**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (5)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:19**

**Generated On: 20 Jul 2016 16:57:04**

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|      |                       |
|------|-----------------------|
| Type | SMOKING QUESTIONNAIRE |
|------|-----------------------|

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|                               |                           |
|-------------------------------|---------------------------|
| Was paper questionnaire used? | Yes <input type="radio"/> |
|-------------------------------|---------------------------|

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|                 |  |
|-----------------|--|
| Reason not done |  |
|-----------------|--|

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|                    |                            |
|--------------------|----------------------------|
| Date of assessment | 07 MAR 2014<br>DD/MMM/YYYY |
|--------------------|----------------------------|

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|                    |                                 |
|--------------------|---------------------------------|
| Time of assessment | 21:30<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? | 18 Years |
|---|----------|

---

|   |  |
|---|--|
| 5. If you are an ex-smoker of cigarettes: For how long have you quit now? |  |
|---|--|

---

|       |          |
|-------|----------|
| Years | 00 Years |
|-------|----------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (5)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:19**

**Generated On: 20 Jul 2016 16:57:04**

---

|        |           |
|--------|-----------|
| Months | 04 Months |
|--------|-----------|

---

|      |         |
|------|---------|
| Days | 00 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 | 00 Years |
|-------|----------|

---

|        |           |
|--------|-----------|
| Months | 04 Months |
|--------|-----------|

---

|      |         |
|------|---------|
| Days | 00 Days |
|------|---------|

---

7. What brand of cigarettes/hand-rolled tobacco did you **NEWPORT**  
predominantly smoke in the last 12 months of smoking?

---

|      |   |
|------|---|
| Time | 15 years ago <input checked="" type="radio"/> |
|------|---|

---

|  |                                       |
|--|---------------------------------------|
| 8. On average, how many Manufactured cigarettes<br>do/did you smoke per day? | None <input checked="" type="radio"/> |
|--|---------------------------------------|

---

|                                    |       |
|------------------------------------|-------|
| Manufactured Cigarettes<br>per day | <hr/> |
|------------------------------------|-------|

---

|   |                                       |
|---|---------------------------------------|
| 8. On average, how many Hand-rolled Cigarettes do/did<br>you smoke per day? | None <input checked="" type="radio"/> |
|---|---------------------------------------|

---

|                                   |       |
|-----------------------------------|-------|
| Hand-rolled Cigarettes<br>per day | <hr/> |
|-----------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (5)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:19**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (6)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:19**

**Generated On: 20 Jul 2016 16:57:04**

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|      |                       |
|------|-----------------------|
| Type | SMOKING QUESTIONNAIRE |
|------|-----------------------|

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|                               |                           |
|-------------------------------|---------------------------|
| Was paper questionnaire used? | Yes <input type="radio"/> |
|-------------------------------|---------------------------|

---

|                 |  |
|-----------------|--|
| Reason not done |  |
|-----------------|--|

---

|                    |                            |
|--------------------|----------------------------|
| Date of assessment | 07 MAR 2014<br>DD/MMM/YYYY |
|--------------------|----------------------------|

---

|                    |                                 |
|--------------------|---------------------------------|
| Time of assessment | 21:30<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? | 18 Years |
|---|----------|

---

|   |  |
|---|--|
| 5. If you are an ex-smoker of cigarettes: For how long have you quit now? |  |
|---|--|

---

|       |          |
|-------|----------|
| Years | 00 Years |
|-------|----------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (6)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:19**

**Generated On: 20 Jul 2016 16:57:04**

---

|        |           |
|--------|-----------|
| Months | 04 Months |
|--------|-----------|

---

|      |         |
|------|---------|
| Days | 00 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 | 00 Years |
|-------|----------|

---

|        |           |
|--------|-----------|
| Months | 04 Months |
|--------|-----------|

---

|      |         |
|------|---------|
| Days | 00 Days |
|------|---------|

---

7. What brand of cigarettes/hand-rolled tobacco did you **NEWPORT**  
predominantly smoke in the last 12 months of smoking?

---

|      |   |
|------|---|
| Time | 20 years ago <input checked="" type="radio"/> |
|------|---|

---

|  |                                       |
|--|---------------------------------------|
| 8. On average, how many Manufactured cigarettes<br>do/did you smoke per day? | None <input checked="" type="radio"/> |
|--|---------------------------------------|

---

Manufactured Cigarettes  
per day

---

|   |                                       |
|---|---------------------------------------|
| 8. On average, how many Hand-rolled Cigarettes do/did<br>you smoke per day? | None <input checked="" type="radio"/> |
|---|---------------------------------------|

---

Hand-rolled Cigarettes  
per day

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (6)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:19**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (7)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:19**

**Generated On: 20 Jul 2016 16:57:04**

---

|      |                       |
|------|-----------------------|
| Type | SMOKING QUESTIONNAIRE |
|------|-----------------------|

---

|                               |                           |
|-------------------------------|---------------------------|
| Was paper questionnaire used? | Yes <input type="radio"/> |
|-------------------------------|---------------------------|

---

|                 |  |
|-----------------|--|
| Reason not done |  |
|-----------------|--|

---

|                    |                            |
|--------------------|----------------------------|
| Date of assessment | 07 MAR 2014<br>DD/MMM/YYYY |
|--------------------|----------------------------|

---

|                    |                                 |
|--------------------|---------------------------------|
| Time of assessment | 21:30<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? | 18 Years |
|---|----------|

---

|   |  |
|---|--|
| 5. If you are an ex-smoker of cigarettes: For how long have you quit now? |  |
|---|--|

---

|       |          |
|-------|----------|
| Years | 00 Years |
|-------|----------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (7)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:19**

**Generated On: 20 Jul 2016 16:57:04**

---

|        |           |
|--------|-----------|
| Months | 04 Months |
|--------|-----------|

---

|      |         |
|------|---------|
| Days | 00 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 | 00 Years |
|-------|----------|

---

|        |           |
|--------|-----------|
| Months | 04 Months |
|--------|-----------|

---

|      |         |
|------|---------|
| Days | 00 Days |
|------|---------|

---

7. What brand of cigarettes/hand-rolled tobacco did you **NEWPORT**  
predominantly smoke in the last 12 months of smoking?

---

|      |   |
|------|---|
| Time | More than 20 years ago <input checked="" type="radio"/> |
|------|---|

---

|  |                                       |
|--|---------------------------------------|
| 8. On average, how many Manufactured cigarettes<br>do/did you smoke per day? | None <input checked="" type="radio"/> |
|--|---------------------------------------|

---

|                                    |       |
|------------------------------------|-------|
| Manufactured Cigarettes<br>per day | <hr/> |
|------------------------------------|-------|

---

|   |                                       |
|---|---------------------------------------|
| 8. On average, how many Hand-rolled Cigarettes do/did<br>you smoke per day? | None <input checked="" type="radio"/> |
|---|---------------------------------------|

---

|                                   |       |
|-----------------------------------|-------|
| Hand-rolled Cigarettes<br>per day | <hr/> |
|-----------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Smoking Questionnaire (SQ) (7)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:19**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Baseline (Day -1)**

**Form: Supplemental Questions**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:20**

**Generated On: 20 Jul 2016 16:57:04**

---

Was paper questionnaire used?

Yes ☒

---

Reason not done

---

Date of Assessment

07 MAR 2014  
DD/MMM/YYYY

---

Time of assessment

21:31

---

1. How long it takes for the subject to complete the SQ

02 minutes

---

Comments (open-end)

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Supplemental Questions (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:20**

**Generated On: 20 Jul 2016 16:57:04**

---

Was paper questionnaire used? Yes ☐

---

Reason not done \_\_\_\_\_

---

Date of Assessment 07 MAR 2014  
DD/MMM/YYYY

---

Time of assessment 21:31

---

1. How long it takes for the subject to complete the SQ 02 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: 1194**

**Folder: Baseline (Day -1)**

**Form: Supplemental Questions (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:20**

**Generated On: 20 Jul 2016 16:57:04**

---

Was paper questionnaire used? Yes ☐

---

Reason not done \_\_\_\_\_

---

Date of Assessment 07 MAR 2014  
DD/MMM/YYYY

---

Time of assessment 21:31

---

1. How long it takes for the subject to complete the SQ 02 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: 1194**

**Folder: Baseline (Day -1)**

**Form: Supplemental Questions (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:20**

**Generated On: 20 Jul 2016 16:57:04**

---

Was paper questionnaire used? Yes ☐

---

Reason not done \_\_\_\_\_

---

Date of Assessment 07 MAR 2014  
DD/MMM/YYYY

---

Time of assessment 21:31

---

1. How long it takes for the subject to complete the SQ 02 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: 1194**

**Folder: Baseline (Day -1)**

**Form: Supplemental Questions (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:20**

**Generated On: 20 Jul 2016 16:57:04**

---

Was paper questionnaire used? Yes ☐

---

Reason not done \_\_\_\_\_

---

Date of Assessment 07 MAR 2014  
DD/MMM/YYYY

---

Time of assessment 21:31

---

1. How long it takes for the subject to complete the SQ 02 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: 1194**

**Folder: Baseline (Day -1)**

**Form: Supplemental Questions (5)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:20**

**Generated On: 20 Jul 2016 16:57:04**

---

Was paper questionnaire used? Yes ☐

---

Reason not done \_\_\_\_\_

---

Date of Assessment 07 MAR 2014  
DD/MMM/YYYY

---

Time of assessment 21:31

---

1. How long it takes for the subject to complete the SQ 02 minutes

---

Question 6. Was the SQ ☐  
self-explaining?

---

Answer Yes ☐

---

Comments (open-end) \_\_\_\_\_

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Supplemental Questions (6)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:20**

**Generated On: 20 Jul 2016 16:57:04**

---

Was paper questionnaire used? Yes ☐

---

Reason not done \_\_\_\_\_

---

Date of Assessment 07 MAR 2014  
DD/MMM/YYYY

---

Time of assessment 21:31

---

1. How long it takes for the subject to complete the SQ 02 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: 1194**

**Folder: Baseline (Day -1)**

**Form: Questionnaire on smoking urges (QSU)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:21**

**Generated On: 20 Jul 2016 16:57:04**

---

|      |     |
|------|-----|
| Type | QSU |
|------|-----|

---

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

---

|                    |             |
|--------------------|-------------|
| Date of assessment | 2014 MAR 07 |
|--------------------|-------------|

DD/MMM/YYYY

---

|                    |       |
|--------------------|-------|
| Time of assessment | 20:03 |
|--------------------|-------|

hour:min 24-hour clock

---

|                   |  |
|-------------------|--|
| Assessment Status | Completed <input checked="" type="radio"/> |
|-------------------|--|

---

|  |  |
|--|--|
| 1. I have a desire for a cigarette right now | Agree <input checked="" type="radio"/> |
|--|--|

---

|   |  |
|---|--|
| 2. Nothing would be better than smoking a cigarette right now | 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 | 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: 1194**

**Folder: Baseline (Day -1)**

**Form: Questionnaire on smoking urges (QSU)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:21**

**Generated On: 20 Jul 2016 16:57:04**

---

7. A cigarette would taste good now Disagree ☐

---

8. I would do almost anything for a cigarette now Strongly 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: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (CEMA, HPMa, HBMA)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:21**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:21**

**Generated On: 20 Jul 2016 16:57:04**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05112450002122 |
|----------------|----------------|

---

|         |      |
|---------|------|
| Analyte | HPMA |
|---------|------|

---

|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

---

|        |     |
|--------|-----|
| Result | 394 |
|--------|-----|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

---

|                |                   |
|----------------|-------------------|
| Sample comment | ANALYZED IN ERROR |
|----------------|-------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |    |
|--------------|----|
| Day of Visit | -1 |
|--------------|----|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-03 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-07 |
|--------------------|-------------|

---

|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

---

|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:21**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

-1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:21**

**Generated On: 20 Jul 2016 16:57:04**

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|                |                |
|----------------|----------------|
| Sample Barcode | 05112450002122 |
|----------------|----------------|

---

|         |      |
|---------|------|
| Analyte | CEMA |
|---------|------|

---

|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

---

|        |      |
|--------|------|
| Result | 50.3 |
|--------|------|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

---

|                |                   |
|----------------|-------------------|
| Sample comment | ANALYZED IN ERROR |
|----------------|-------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |    |
|--------------|----|
| Day of Visit | -1 |
|--------------|----|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-03 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-07 |
|--------------------|-------------|

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|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

---

|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:21**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

-1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (CEMA, HPMa, HBMA) (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:21**

**Generated On: 20 Jul 2016 16:57:04**

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|                |                |
|----------------|----------------|
| Sample Barcode | 05112450002122 |
|----------------|----------------|

---

|         |      |
|---------|------|
| Analyte | HBMA |
|---------|------|

---

|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

---

|        |     |
|--------|-----|
| Result | 105 |
|--------|-----|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

---

|                |                   |
|----------------|-------------------|
| Sample comment | ANALYZED IN ERROR |
|----------------|-------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |    |
|--------------|----|
| Day of Visit | -1 |
|--------------|----|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-03 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-07 |
|--------------------|-------------|

---

|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

---

|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:21**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

-1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (NNN, NNAL)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:21**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (NNN, NNAL) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:21**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112460002515    |
| Analyte                   | NNAL              |
| Sample type               | URINE             |
| Result                    | 36.1              |
| Result Unit               | PG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | -1                |
| Celerion Study Number     | AA99128-04        |
| Date of Collection        | 2014-MAR-07       |
| Timepoint-minutes         |                   |
| Urine Start Day           |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (NNN, NNAL) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:21**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

-1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (NNN, NNAL) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:21**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112460002515    |
| Analyte                   | NNN               |
| Sample type               | URINE             |
| Result                    | 1.47              |
| Result Unit               | PG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | -1                |
| Celerion Study Number     | AA99128-04        |
| Date of Collection        | 2014-MAR-07       |
| Timepoint-minutes         |                   |
| Urine Start Day           |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (NNN, NNAL) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:21**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

-1

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (HEMA)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:21**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

URINE

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (HEMA) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:21**

**Generated On: 20 Jul 2016 16:57:04**

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|                |                |
|----------------|----------------|
| Sample Barcode | 05112470001255 |
|----------------|----------------|

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|         |      |
|---------|------|
| Analyte | HEMA |
|---------|------|

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|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

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|        |      |
|--------|------|
| Result | 3.00 |
|--------|------|

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|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

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|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

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|                |                   |
|----------------|-------------------|
| Sample comment | ANALYZED IN ERROR |
|----------------|-------------------|

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|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

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|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

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|              |    |
|--------------|----|
| Day of Visit | -1 |
|--------------|----|

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|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-05 |
|-----------------------|------------|

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|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-07 |
|--------------------|-------------|

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|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

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|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (HEMA) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:21**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

-1

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:22**

**Generated On: 20 Jul 2016 16:57:04**

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Sample type

URINE

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:22**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112480000661    |
| Analyte                   | COT               |
| Sample type               | URINE             |
| Result                    | 935               |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | -1                |
| Celerion Study Number     | AA99128-06        |
| Date of Collection        | 2014-MAR-07       |
| Timepoint-minutes         |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:22**

**Generated On: 20 Jul 2016 16:57:04**

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Urine Start Day

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Urine End Day

-1

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:22**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112480000661    |
| Analyte                   | COT-GLUC          |
| Sample type               | URINE             |
| Result                    | 975               |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | -1                |
| Celerion Study Number     | AA99128-06        |
| Date of Collection        | 2014-MAR-07       |
| Timepoint-minutes         |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:22**

**Generated On: 20 Jul 2016 16:57:04**

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Urine Start Day

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Urine End Day

-1

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:22**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112480000661    |
| Analyte                   | NIC               |
| Sample type               | URINE             |
| Result                    | 259               |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | -1                |
| Celerion Study Number     | AA99128-06        |
| Date of Collection        | 2014-MAR-07       |
| Timepoint-minutes         |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:22**

**Generated On: 20 Jul 2016 16:57:04**

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Urine Start Day

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Urine End Day

-1

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:22**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112480000661    |
| Analyte                   | NIC-GLUC          |
| Sample type               | URINE             |
| Result                    | 138               |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | -1                |
| Celerion Study Number     | AA99128-06        |
| Date of Collection        | 2014-MAR-07       |
| Timepoint-minutes         |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:22**

**Generated On: 20 Jul 2016 16:57:04**

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Urine Start Day

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Urine End Day

-1

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(5)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:22**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112480000661    |
| Analyte                   | THCOT             |
| Sample type               | URINE             |
| Result                    | 1360              |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | -1                |
| Celerion Study Number     | AA99128-06        |
| Date of Collection        | 2014-MAR-07       |
| Timepoint-minutes         |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(5)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:22**

**Generated On: 20 Jul 2016 16:57:04**

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Urine Start Day

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Urine End Day

-1

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(6)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:22**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112480000661    |
| Analyte                   | THCOT-GLUC        |
| Sample type               | URINE             |
| Result                    | 433               |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | -1                |
| Celerion Study Number     | AA99128-06        |
| Date of Collection        | 2014-MAR-07       |
| Timepoint-minutes         |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(6)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:22**

**Generated On: 20 Jul 2016 16:57:04**

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Urine Start Day

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Urine End Day

-1

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (3-OH BaP)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:22**

**Generated On: 20 Jul 2016 16:57:04**

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Sample type

URINE

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (3-OH BaP) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:22**

**Generated On: 20 Jul 2016 16:57:04**

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|                |                |
|----------------|----------------|
| Sample Barcode | 05112490001257 |
|----------------|----------------|

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|         |          |
|---------|----------|
| Analyte | 3-OH BAP |
|---------|----------|

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|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

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|        |            |
|--------|------------|
| Result | BLQ<(25.0) |
|--------|------------|

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|             |       |
|-------------|-------|
| Result Unit | FG/ML |
|-------------|-------|

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|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

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|                |                   |
|----------------|-------------------|
| Sample comment | ANALYZED IN ERROR |
|----------------|-------------------|

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|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

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|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

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|              |    |
|--------------|----|
| Day of Visit | -1 |
|--------------|----|

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|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-07 |
|-----------------------|------------|

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|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-07 |
|--------------------|-------------|

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|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

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|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (3-OH BaP) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:22**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

-1

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:22**

**Generated On: 20 Jul 2016 16:57:04**

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Sample type

URINE

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:22**

**Generated On: 20 Jul 2016 16:57:04**

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|                |                |
|----------------|----------------|
| Sample Barcode | 05112510001279 |
|----------------|----------------|

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|         |      |
|---------|------|
| Analyte | 1-NA |
|---------|------|

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|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

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|        |      |
|--------|------|
| Result | 26.8 |
|--------|------|

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|             |       |
|-------------|-------|
| Result Unit | PG/ML |
|-------------|-------|

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|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

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|                |                   |
|----------------|-------------------|
| Sample comment | ANALYZED IN ERROR |
|----------------|-------------------|

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|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

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|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

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|              |    |
|--------------|----|
| Day of Visit | -1 |
|--------------|----|

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|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-09 |
|-----------------------|------------|

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|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-07 |
|--------------------|-------------|

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|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

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|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:22**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

-1

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:22**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112510001279    |
| Analyte                   | 2-NA              |
| Sample type               | URINE             |
| Result                    | 6.94              |
| Result Unit               | PG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | -1                |
| Celerion Study Number     | AA99128-09        |
| Date of Collection        | 2014-MAR-07       |
| Timepoint-minutes         |                   |
| Urine Start Day           |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:22**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

-1

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:22**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112510001279    |
| Analyte                   | 4-ABP             |
| Sample type               | URINE             |
| Result                    | 5.08              |
| Result Unit               | PG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | -1                |
| Celerion Study Number     | AA99128-09        |
| Date of Collection        | 2014-MAR-07       |
| Timepoint-minutes         |                   |
| Urine Start Day           |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:22**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

-1

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:22**

**Generated On: 20 Jul 2016 16:57:04**

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|                |                |
|----------------|----------------|
| Sample Barcode | 05112510001279 |
|----------------|----------------|

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|         |       |
|---------|-------|
| Analyte | O-TOL |
|---------|-------|

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|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

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|        |            |
|--------|------------|
| Result | BLQ<(50.0) |
|--------|------------|

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|             |       |
|-------------|-------|
| Result Unit | PG/ML |
|-------------|-------|

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|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

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|                |                   |
|----------------|-------------------|
| Sample comment | ANALYZED IN ERROR |
|----------------|-------------------|

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|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

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|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

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|              |    |
|--------------|----|
| Day of Visit | -1 |
|--------------|----|

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|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-09 |
|-----------------------|------------|

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|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-07 |
|--------------------|-------------|

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|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

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|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:22**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

-1

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (11-dTXb2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:21**

**Generated On: 20 Jul 2016 16:57:04**

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Sample type

URINE

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (11-dTXb2) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:21**

**Generated On: 20 Jul 2016 16:57:04**

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|                |                |
|----------------|----------------|
| Sample Barcode | 05112530000400 |
|----------------|----------------|

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|         |          |
|---------|----------|
| Analyte | 11-DTXB2 |
|---------|----------|

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|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

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|        |     |
|--------|-----|
| Result | 178 |
|--------|-----|

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|             |       |
|-------------|-------|
| Result Unit | PG/ML |
|-------------|-------|

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|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

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|                |                   |
|----------------|-------------------|
| Sample comment | ANALYZED IN ERROR |
|----------------|-------------------|

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|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

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|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

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|              |    |
|--------------|----|
| Day of Visit | -1 |
|--------------|----|

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|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-11 |
|-----------------------|------------|

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|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-07 |
|--------------------|-------------|

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|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

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|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (11-dTXb2) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:21**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

-1

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (iPF2a-III)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:21**

**Generated On: 20 Jul 2016 16:57:04**

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Sample type

URINE

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (iPF2a-III) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:21**

**Generated On: 20 Jul 2016 16:57:04**

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|                |                |
|----------------|----------------|
| Sample Barcode | 05112540000400 |
|----------------|----------------|

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|         |           |
|---------|-----------|
| Analyte | IPF2A-III |
|---------|-----------|

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|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

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|        |      |
|--------|------|
| Result | 94.3 |
|--------|------|

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|             |       |
|-------------|-------|
| Result Unit | PG/ML |
|-------------|-------|

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|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

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|                |                   |
|----------------|-------------------|
| Sample comment | ANALYZED IN ERROR |
|----------------|-------------------|

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|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

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|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

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|              |    |
|--------------|----|
| Day of Visit | -1 |
|--------------|----|

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|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-12 |
|-----------------------|------------|

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|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-07 |
|--------------------|-------------|

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|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

---

|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (iPF2a-III) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:21**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

-1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (1-OHP)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:22**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (1-OHP) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:22**

**Generated On: 20 Jul 2016 16:57:04**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05115190001563 |
|----------------|----------------|

---

|         |       |
|---------|-------|
| Analyte | 1-OHP |
|---------|-------|

---

|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | PG/ML |
|-------------|-------|

---

|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | NOT ANALYZED IN ERROR |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |    |
|--------------|----|
| Day of Visit | -1 |
|--------------|----|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99598-03 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-07 |
|--------------------|-------------|

---

|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

---

|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (1-OHP) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:22**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

-1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (SPMA, SBMA)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:21**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (SPMA, SBMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:21**

**Generated On: 20 Jul 2016 16:57:04**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05115170001541 |
|----------------|----------------|

---

|         |      |
|---------|------|
| Analyte | SBMA |
|---------|------|

---

|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | NOT ANALYZED IN ERROR |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |    |
|--------------|----|
| Day of Visit | -1 |
|--------------|----|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99598-01 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-07 |
|--------------------|-------------|

---

|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

---

|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (SPMA, SBMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:21**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

-1

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (SPMA, SBMA) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:21**

**Generated On: 20 Jul 2016 16:57:04**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05115170001541 |
|----------------|----------------|

---

|         |      |
|---------|------|
| Analyte | SPMA |
|---------|------|

---

|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | NOT ANALYZED IN ERROR |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |    |
|--------------|----|
| Day of Visit | -1 |
|--------------|----|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99598-01 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-07 |
|--------------------|-------------|

---

|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

---

|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (SPMA, SBMA) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:21**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

-1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (MHBMA)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:21**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (MHBMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:21**

**Generated On: 20 Jul 2016 16:57:04**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05115180001563 |
|----------------|----------------|

---

|         |       |
|---------|-------|
| Analyte | MHBMA |
|---------|-------|

---

|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | NOT ANALYZED IN ERROR |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |  |
|--------------|--|
| Day of Visit |  |
|--------------|--|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99598-02 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-07 |
|--------------------|-------------|

---

|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

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|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (MHBMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:21**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

-1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (Creatinine)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:22**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (Creatinine) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:22**

**Generated On: 20 Jul 2016 16:57:04**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05115160001257 |
|----------------|----------------|

---

|         |            |
|---------|------------|
| Analyte | CREATININE |
|---------|------------|

---

|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

---

|        |      |
|--------|------|
| Result | 51.1 |
|--------|------|

---

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

---

|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

---

|                |                       |
|----------------|-----------------------|
| 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-MAR-07 |
|--------------------|-------------|

---

|                   |       |
|-------------------|-------|
| Timepoint-minutes | <hr/> |
|-------------------|-------|

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|                 |       |
|-----------------|-------|
| Urine Start Day | <hr/> |
|-----------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day -1)**

**Form: Biomarker-Urine (Creatinine) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:22**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

-1

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Date of Visit**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

Date of Visit

08 MAR 2014  
DD/MMM/YYYY

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Randomization**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

|                                 |      |
|---------------------------------|------|
| Randomization number (4 digits) | 1054 |
|---------------------------------|------|

---

|                |  |
|----------------|--|
| 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: 1194**

**Folder: Baseline (Day 0)**

**Form: Vital Signs**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

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 09:16  
hour:min 24-hour clock

---

Pulse rate 57  
beats per minute

---

Respiratory rate 16  
breaths per minute

---

Blood Pressure (systolic) 133  
mmHg

---

Blood Pressure (diastolic) 79  
mmHg

---

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Gas Transfer**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:24**

**Generated On: 20 Jul 2016 16:57:04**

---

Was the Gas Transfer performed? Yes ☒

---

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

---

Category \_\_\_\_\_

---

Position SITTING

---

Time of assessment 06:34

---

DLCO value 25.11  
ml/min/mmHg

---

KCO value 1.29  
mmol/min/kPa/L

---

DLCO/VA value 3.87  
mL/min/mmHg/L

---

Interpretation Abnormal ☒

---

If Abnormal, Clinical Significance Not clinically significant ☒

---

If Not Clinically Significant or Clinically Significant, Please MILD DECREASE DLCO specify the finding(s)

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lung Volume Measurements**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:24**

**Generated On: 20 Jul 2016 16:57:04**

---

Were the Lung Volume Measurements performed? Yes ☒

---

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

---

Category \_\_\_\_\_

---

Position SITTING

---

Time of assessment 06:50

---

VC value 5.08  
L

---

TLC value 6.22  
L

---

IC value 2.86  
L

---

FRC value 3.36  
L

---

Interpretation Normal ☒

---

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: 1194**

**Folder: Baseline (Day 0)**

**Form: Spirometry with a short-acting bronchodilator**

**Data signed: (hcoleman1) 18 Jun 2015 20:59:09**

**Generated On: 20 Jul 2016 16:57:04**

---

|  |                                      |
|--|--------------------------------------|
| Was the Spirometry with a short-acting bronchodilator performed? | Yes <input checked="" type="radio"/> |
|--|--------------------------------------|

---

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

---

---

|          |   |
|----------|---|
| Category | With short-acting bronchodilator <input checked="" type="radio"/> |
|----------|---|

---

---

|          |         |
|----------|---------|
| Position | SITTING |
|----------|---------|

---

---

|                    |       |
|--------------------|-------|
| Time of assessment | 07:18 |
|--------------------|-------|

---

---

|                        |                   |
|------------------------|-------------------|
| Name of bronchodilator | ALBUTEROL SULFATE |
|------------------------|-------------------|

---

---

|      |         |
|------|---------|
| Dose | 180 MCG |
|------|---------|

---

---

|                     |        |
|---------------------|--------|
| Predicted FVC value | 4.53 L |
|---------------------|--------|

---

---

|                         |        |
|-------------------------|--------|
| Best measured FVC value | 4.97 L |
|-------------------------|--------|

---

---

|                                |       |
|--------------------------------|-------|
| Percent of predicted FVC value | 109 % |
|--------------------------------|-------|

---

---

|                          |        |
|--------------------------|--------|
| Best measured FEV1 value | 3.43 L |
|--------------------------|--------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Spirometry with a short-acting bronchodilator**

**Data signed: (hcoleman1) 18 Jun 2015 20:59:09**

**Generated On: 20 Jul 2016 16:57:04**

---

|                      |           |
|----------------------|-----------|
| Predicted FEV1 value | 3.78<br>L |
|----------------------|-----------|

---

|                                 |         |
|---------------------------------|---------|
| Percent of predicted FEV1 value | 90<br>% |
|---------------------------------|---------|

---

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

---

|                 |             |
|-----------------|-------------|
| MEF 25/75 value | 2.16<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: 1194**

**Folder: Baseline (Day 0)**

**Form: Haematology**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:23**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Baseline (Day 0)**

**Form: Clinical Chemistry**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:23**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Baseline (Day 0)**

**Form: Urine analysis**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:23**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Baseline (Day 0)**

**Form: Plasma Nicotine Sample**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:24**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

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

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 08 MAR 2014 |
|---------------------|-------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 20:20 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Plasma Cotinine Sample**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:24**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

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

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 08 MAR 2014 |
|---------------------|-------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 20:20 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: CoHb Blood Sample <D0> (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:23**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

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

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 08 MAR 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 | 06:10 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: CoHb Blood Sample <D0> (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:23**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

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

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 08 MAR 2014 |
|---------------------|-------------|

---

|           |  |
|-----------|--|
| Timepoint | 20:00 - 21:30 <input checked="" type="radio"/> |
|-----------|--|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 20:20 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Oxysterols**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:24**

**Generated On: 20 Jul 2016 16:57:04**

---

|          |       |
|----------|-------|
| 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 | 08 MAR 2014 |
|---------------------|-------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 06:10 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: CO Breath Test (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:23**

**Generated On: 20 Jul 2016 16:57:04**

---

|                     |       |
|---------------------|-------|
| 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 | 07:25 |
|---|-------|

---

|             |    |
|-------------|----|
| Result(ppm) | 17 |
|-------------|----|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: CO Breath Test (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:23**

**Generated On: 20 Jul 2016 16:57:04**

---

|                     |       |
|---------------------|-------|
| 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 | 12:06 |
|---|-------|

---

|             |    |
|-------------|----|
| Result(ppm) | 23 |
|-------------|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: CO Breath Test (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:23**

**Generated On: 20 Jul 2016 16:57:04**

---

|                     |       |
|---------------------|-------|
| 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 | 16:12 |
|---|-------|

---

|             |    |
|-------------|----|
| Result(ppm) | 18 |
|-------------|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: CO Breath Test (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:23**

**Generated On: 20 Jul 2016 16:57:04**

---

|                     |       |
|---------------------|-------|
| 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 | 20:18 |
|---|-------|

---

|             |    |
|-------------|----|
| Result(ppm) | 20 |
|-------------|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: CYP2A6 activity Sample**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:24**

**Generated On: 20 Jul 2016 16:57:04**

---

|          |       |
|----------|-------|
| 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

---

08 MAR 2014

06:10

trans-3'-hydroxyc  
otinine

---

08 MAR 2014

06:10

cotinine

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: CYP1A2 activity Sample**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:24**

**Generated On: 20 Jul 2016 16:57:04**

---

|                                |                        |
|--------------------------------|------------------------|
| Time of caffeine tablet intake | 11:03                  |
|                                | 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    |
|--|---|--------------|
| 08 MAR 2014                              | 17:00   | Caffeine     |
| 08 MAR 2014                              | 17:00   | Paraxanthine |

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Risk Marker: hs-CRP, fibrinogen, homocysteine, LDL, HDL,  
sICAM-1, HbA1c, Apo A1, Apo B**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:24**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

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

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 08 MAR 2014 |
|---------------------|-------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 06:10 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: 24 hour urine collections**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

|            |                            |
|------------|----------------------------|
| Start Date | 08 MAR 2014<br>DD/MMM/YYYY |
|------------|----------------------------|

---

|            |                                 |
|------------|---------------------------------|
| Start Time | 06:09<br>hour:min 24-hour clock |
|------------|---------------------------------|

---

|          |                            |
|----------|----------------------------|
| End Date | 09 MAR 2014<br>DD/MMM/YYYY |
|----------|----------------------------|

---

|          |                                 |
|----------|---------------------------------|
| End Time | 06:13<br>hour:min 24-hour clock |
|----------|---------------------------------|

---

|        |            |
|--------|------------|
| Volume | 2852<br>mL |
|--------|------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Sample Urine Collection**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

Were samples for 24h collected? Yes ☒

---

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

---

How many primary tubes were collected? 14

---

How many back up tubes were collected? 13

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:39**

**Generated On: 20 Jul 2016 16:57:04**

---

Date of Birth

(b) (6)

---

Date of assessment  
DD/MMM/YYYY

2014 MAR 08  
DD/MMM/YYYY

---

Time of assessment

06:06  
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?

Mild ☐

4. Desire or craving to smoke

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:39**

**Generated On: 20 Jul 2016 16:57:04**

---

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? 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? None ☐

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: 1194**

**Folder: Baseline (Day 0)**

**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:39**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Baseline (Day 0)**

**Form: Cough Assessment**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:39**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

---

|                                   |                            |
|-----------------------------------|----------------------------|
| Date of assessment<br>DD/MMM/YYYY | 2014 MAR 08<br>DD/MMM/YYYY |
|-----------------------------------|----------------------------|

---

---

|                    |                                 |
|--------------------|---------------------------------|
| Time of assessment | 06:05<br>hour:min 24-hour clock |
|--------------------|---------------------------------|

---

---

|                   |  |
|-------------------|--|
| Assessment Status | Completed <input checked="" type="radio"/> |
|-------------------|--|

---

---

|  |                                     |
|--|-------------------------------------|
| Have you experienced a regular need to cough e.g. 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 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: 1194**

**Folder: Baseline (Day 0)**

**Form: Bio-banking (Transcriptomics)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:39**

**Generated On: 20 Jul 2016 16:57:04**

---

Was a Bio-banking sample for transcriptomics taken?

Yes ☒

---

Time of Sample Collection

06:10  
hour:min 24-hour clock

---

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

Yes ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Bio-banking (Biomarkers of exposure and risk markers)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:39**

**Generated On: 20 Jul 2016 16:57:04**

---

Was a Bio-banking sample for biomarkers of exposure  
and risk markers taken?

Yes ☒

---

Time of Sample Collection

06:10  
hour:min 24-hour clock

---

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

Yes ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Bio-banking (nasal epithelial collection/buccal collection)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:39**

**Generated On: 20 Jul 2016 16:57:04**

---

|   |                                      |
|---|--------------------------------------|
| Was a Bio-banking sample for nasal epithelial collection/buccal collection taken? | Yes <input checked="" type="radio"/> |
|---|--------------------------------------|

---

|                           |                        |
|---------------------------|------------------------|
| Time of Buccal Collection | 17:14                  |
|                           | hour:min 24-hour clock |

---

|                                     |                        |
|-------------------------------------|------------------------|
| Time of Nasal Epithelial Collection | 17:12                  |
|                                     | hour:min 24-hour clock |

---

|   |                           |
|---|---------------------------|
| Was the subject fasting for at least 30 minutes at time of sample collection? | Yes <input type="radio"/> |
|---|---------------------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

Transmission Type Cumulative ☐

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex M

---

Subject Date of Birth (b) (6) \_\_\_\_\_

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID W715942

---

Actual Collection Date 2014 03 08

---

Actual Collection Time 06:10

---

Specimen Condition \_\_\_\_\_

---

Battery ID RC1029

---

Battery Name TRIGLYCERIDES

---

Lab Test ID RCT19

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | TRIGLYCERIDES (GPO)                   |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 57                                    |
| Reported Numeric Result           | 57                                    |
| Reference Range low               | 50                                    |
| Reference Range high              | 321                                   |
| 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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

Transmission Type Cumulative ☒

---

Subject ID or Number 

---

---

Subject Sex M

---

Subject Date of Birth (b) (6) 

---

Visit Name 

---

---

Visit Type Scheduled ☒

---

Accession ID W715942

---

Actual Collection Date 2014 03 08

---

Actual Collection Time 06:10

---

Specimen Condition 

---

---

Battery ID RC1092

---

Battery Name FASTING GLUCOSE

---

Lab Test ID RCT142

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | FASTING GLUCOSE                       |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 85                                    |
| Reported Numeric Result           | 85                                    |
| 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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

Transmission Type Cumulative ☐

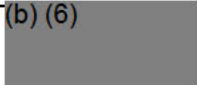
---

Subject ID or Number \_\_\_\_\_

---

Subject Sex M

---

Subject Date of Birth (b) (6) 

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID W715942

---

Actual Collection Date 2014 03 08

---

Actual Collection Time 06:10

---

Specimen Condition \_\_\_\_\_

---

Battery ID RC272

---

Battery Name TOTAL CHOLESTEROL

---

Lab Test ID RCT20

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

Lab Test Name

CHOLESTEROL (HIGH  
PERFORMANCE)

---

Test ID

---

Test Status

Done ☒

---

Reported Text Result

135

---

Reported Numeric Result

135

---

Reference Range low

150

---

Reference Range high

264

---

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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Text Result

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

Low ☒

Clinically Significant?

No ☒

Comment

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

Transmission Type Cumulative ☐


---

Subject ID or Number \_\_\_\_\_

---

Subject Sex M

---

Subject Date of Birth (b) (6) 

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID W715942

---

Actual Collection Date 2014 03 08

---

Actual Collection Time 06:10

---

Specimen Condition \_\_\_\_\_

---

Battery ID RC9255

---

Battery Name CHEMISTRY PANEL

---

Lab Test ID RCT1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | TOTAL BILIRUBIN                       |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 0.5                                   |
| Reported Numeric Result           | 0.5                                   |
| 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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (5)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

Transmission Type Cumulative ☐

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex M

---

Subject Date of Birth (b) (6)

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID W715942

---

Actual Collection Date 2014 03 08

---

Actual Collection Time 06:10

---

Specimen Condition \_\_\_\_\_

---

Battery ID RC9255

---

Battery Name CHEMISTRY PANEL

---

Lab Test ID RCT12

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (5)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | TOTAL PROTEIN                         |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| 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                    |                                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (5)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (6)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

Transmission Type Cumulative ☐

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex M

---

Subject Date of Birth (b) (6) 

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID W715942

---

Actual Collection Date 2014 03 08

---

Actual Collection Time 06:10

---

Specimen Condition \_\_\_\_\_

---

Battery ID RC9255

---

Battery Name CHEMISTRY PANEL

---

Lab Test ID RCT13

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (6)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | ALBUMIN                               |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 4.3                                   |
| Reported Numeric Result           | 4.3                                   |
| 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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (6)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (7)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

Transmission Type Cumulative ☒

---

Subject ID or Number 

---

---

Subject Sex M

---

Subject Date of Birth (b) (6) 

---

Visit Name 

---

---

Visit Type Scheduled ☒

---

Accession ID W715942

---

Actual Collection Date 2014 03 08

---

Actual Collection Time 06:10

---

Specimen Condition 

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---

Battery ID RC9255

---

Battery Name CHEMISTRY PANEL

---

Lab Test ID RCT1407

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (7)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                            |
|-----------------------------------|----------------------------|
| Lab Test Name                     | ALKALINE PHOSPHATASE       |
| Test ID                           |                            |
| Test Status                       | Done <input type="radio"/> |
| Reported Text Result              | 65                         |
| Reported Numeric Result           | 65                         |
| Reference Range low               | 31                         |
| Reference Range high              | 129                        |
| 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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (7)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (8)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

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|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

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|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

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|              |         |
|--------------|---------|
| Accession ID | W715942 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 08 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:10 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

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|            |        |
|------------|--------|
| Battery ID | RC9255 |
|------------|--------|

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|              |                 |
|--------------|-----------------|
| Battery Name | CHEMISTRY PANEL |
|--------------|-----------------|

---

|             |         |
|-------------|---------|
| Lab Test ID | RCT1408 |
|-------------|---------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (8)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                               |
|-----------------------------------|-------------------------------|
| Lab Test Name                     | LDH                           |
| Test ID                           |                               |
| Test Status                       | Done <input type="checkbox"/> |
| Reported Text Result              | 156                           |
| Reported Numeric Result           | 156                           |
| 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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (8)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

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Comment

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (9)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

Transmission Type Cumulative ☒

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex M

---

Subject Date of Birth (b) (6)

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☒

---

Accession ID W715942

---

Actual Collection Date 2014 03 08

---

Actual Collection Time 06:10

---

Specimen Condition \_\_\_\_\_

---

Battery ID RC9255

---

Battery Name CHEMISTRY PANEL

---

Lab Test ID RCT15



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (9)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | SERUM SODIUM                          |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 142                                   |
| Reported Numeric Result           | 142                                   |
| 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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (9)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (10)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

Transmission Type Cumulative ☒

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex M

---

Subject Date of Birth (b) (6) 

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☒

---

Accession ID W715942

---

Actual Collection Date 2014 03 08

---

Actual Collection Time 06:10

---

Specimen Condition \_\_\_\_\_

---

Battery ID RC9255

---

Battery Name CHEMISTRY PANEL

---

Lab Test ID RCT16

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (10)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |  |
|-----------------------------------|--|
| Lab Test Name                     | SERUM POTASSIUM                          |
| Test ID                           |  |
| Test Status                       | Done <input checked="" type="checkbox"/> |
| Reported Text Result              | 4.6                                      |
| Reported Numeric Result           | 4.6                                      |
| 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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (10)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (11)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

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Transmission Type Cumulative ☒

---

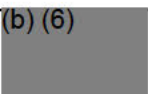
Subject ID or Number 

---

---

Subject Sex M

---

Subject Date of Birth (b) (6) 

---

Visit Name 

---

---

Visit Type Scheduled ☒

---

Accession ID W715942

---

Actual Collection Date 2014 03 08

---

Actual Collection Time 06:10

---

Specimen Condition 

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---

Battery ID RC9255

---

Battery Name CHEMISTRY PANEL

---

Lab Test ID RCT29

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (11)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | DIRECT BILIRUBIN                      |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 0.1                                   |
| Reported Numeric Result           | 0.1                                   |
| 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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (11)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (12)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

---

|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

---

|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W715942 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 08 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:10 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

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|            |        |
|------------|--------|
| Battery ID | RC9255 |
|------------|--------|

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|              |                 |
|--------------|-----------------|
| Battery Name | CHEMISTRY PANEL |
|--------------|-----------------|

---

|             |      |
|-------------|------|
| Lab Test ID | RCT3 |
|-------------|------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (12)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | GGT                                   |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 18                                    |
| Reported Numeric Result           | 18                                    |
| Reference Range low               | 10                                    |
| Reference Range high              | 61                                    |
| 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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (12)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (13)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

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|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

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|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W715942 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 08 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:10 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

---

|            |        |
|------------|--------|
| Battery ID | RC9255 |
|------------|--------|

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|              |                 |
|--------------|-----------------|
| Battery Name | CHEMISTRY PANEL |
|--------------|-----------------|

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|             |        |
|-------------|--------|
| Lab Test ID | RCT392 |
|-------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (13)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

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|               |                           |
|---------------|---------------------------|
| Lab Test Name | CREATININE (RATE BLANKED) |
|---------------|---------------------------|

---

|         |       |
|---------|-------|
| Test ID | <hr/> |
|---------|-------|

---

|             |                                       |
|-------------|---------------------------------------|
| Test Status | Done <input checked="" type="radio"/> |
|-------------|---------------------------------------|

---

|                      |     |
|----------------------|-----|
| Reported Text Result | 1.2 |
|----------------------|-----|

---

|                         |     |
|-------------------------|-----|
| Reported Numeric Result | 1.2 |
|-------------------------|-----|

---

|                     |     |
|---------------------|-----|
| Reference Range low | 0.5 |
|---------------------|-----|

---

|                      |     |
|----------------------|-----|
| Reference Range high | 1.2 |
|----------------------|-----|

---

|             |       |
|-------------|-------|
| 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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (13)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (14)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

---

|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

---

|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

---

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

---

|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W715942 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 08 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:10 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

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|            |        |
|------------|--------|
| Battery ID | RC9255 |
|------------|--------|

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|              |                 |
|--------------|-----------------|
| Battery Name | CHEMISTRY PANEL |
|--------------|-----------------|

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|             |      |
|-------------|------|
| Lab Test ID | RCT4 |
|-------------|------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (14)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                            |
|-----------------------------------|----------------------------|
| Lab Test Name                     | ALT (SGPT)                 |
| Test ID                           |                            |
| Test Status                       | Done <input type="radio"/> |
| Reported Text Result              | 14                         |
| Reported Numeric Result           | 14                         |
| Reference Range low               | 6                          |
| Reference Range high              | 43                         |
| 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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (14)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (15)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

---

|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

---

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

---

|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W715942 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 08 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:10 |
|------------------------|-------|

---

|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

---

|            |        |
|------------|--------|
| Battery ID | RC9255 |
|------------|--------|

---

|              |                 |
|--------------|-----------------|
| Battery Name | CHEMISTRY PANEL |
|--------------|-----------------|

---

|             |      |
|-------------|------|
| Lab Test ID | RCT5 |
|-------------|------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (15)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | AST (SGOT)                            |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 17                                    |
| Reported Numeric Result           | 17                                    |
| Reference Range low               | 11                                    |
| Reference Range high              | 36                                    |
| 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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (15)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (16)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

---

|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

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|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W715942 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 08 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:10 |
|------------------------|-------|

---

|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

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|            |        |
|------------|--------|
| Battery ID | RC9255 |
|------------|--------|

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|              |                 |
|--------------|-----------------|
| Battery Name | CHEMISTRY PANEL |
|--------------|-----------------|

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|             |      |
|-------------|------|
| Lab Test ID | RCT6 |
|-------------|------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (16)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | UREA NITROGEN                         |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| 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                    |                                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (16)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (17)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

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|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

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|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

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|              |         |
|--------------|---------|
| Accession ID | W715942 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 08 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:10 |
|------------------------|-------|

---

|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

---

|            |        |
|------------|--------|
| Battery ID | HM1604 |
|------------|--------|

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|              |                                   |
|--------------|-----------------------------------|
| Battery Name | HEMATOLOGY<br>&DIFFERENTIAL PANEL |
|--------------|-----------------------------------|

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|             |       |
|-------------|-------|
| Lab Test ID | HMT10 |
|-------------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (17)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | MONOCYTES                             |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 0.31                                  |
| Reported Numeric Result           | 0.31                                  |
| 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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (17)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

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Alert Flag

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Clinically Significant?

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Comment

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (18)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

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|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

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|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W715942 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 08 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:10 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

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|            |        |
|------------|--------|
| Battery ID | HM1604 |
|------------|--------|

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|              |                                   |
|--------------|-----------------------------------|
| Battery Name | HEMATOLOGY<br>&DIFFERENTIAL PANEL |
|--------------|-----------------------------------|

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|             |        |
|-------------|--------|
| Lab Test ID | HMT100 |
|-------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (18)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | MCH                                   |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 32                                    |
| Reported Numeric Result           | 32                                    |
| 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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (18)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

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Reported Result Type

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Alert Flag

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Clinically Significant?

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Comment

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (19)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

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|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

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|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

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|              |         |
|--------------|---------|
| Accession ID | W715942 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 08 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:10 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

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|            |        |
|------------|--------|
| Battery ID | HM1604 |
|------------|--------|

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|              |                                   |
|--------------|-----------------------------------|
| Battery Name | HEMATOLOGY<br>&DIFFERENTIAL PANEL |
|--------------|-----------------------------------|

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|             |        |
|-------------|--------|
| Lab Test ID | HMT102 |
|-------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (19)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | MCHC                                  |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 34                                    |
| Reported Numeric Result           | 34                                    |
| 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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (19)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

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Clinically Significant?

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Comment

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (20)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

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|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

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|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W715942 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 08 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:10 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

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|            |        |
|------------|--------|
| Battery ID | HM1604 |
|------------|--------|

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|              |                                   |
|--------------|-----------------------------------|
| Battery Name | HEMATOLOGY<br>&DIFFERENTIAL PANEL |
|--------------|-----------------------------------|

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|             |       |
|-------------|-------|
| Lab Test ID | HMT11 |
|-------------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (20)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | EOSINOPHILS                           |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 0.21                                  |
| Reported Numeric Result           | 0.21                                  |
| 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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (20)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

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Comment

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (21)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

---

|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

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|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

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|              |         |
|--------------|---------|
| Accession ID | W715942 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 08 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:10 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

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|            |        |
|------------|--------|
| Battery ID | HM1604 |
|------------|--------|

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|              |                                   |
|--------------|-----------------------------------|
| Battery Name | HEMATOLOGY<br>&DIFFERENTIAL PANEL |
|--------------|-----------------------------------|

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|             |       |
|-------------|-------|
| Lab Test ID | HMT12 |
|-------------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (21)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |  |
|-----------------------------------|--|
| Lab Test Name                     | BASOPHILS                                |
| Test ID                           |  |
| Test Status                       | Done <input checked="" type="checkbox"/> |
| Reported Text Result              | 0.02                                     |
| Reported Numeric Result           | 0.02                                     |
| 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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (21)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

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Clinically Significant?

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Comment

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (22)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

---

|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W715942 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 08 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:10 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

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|            |        |
|------------|--------|
| Battery ID | HM1604 |
|------------|--------|

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|              |                                   |
|--------------|-----------------------------------|
| Battery Name | HEMATOLOGY<br>&DIFFERENTIAL PANEL |
|--------------|-----------------------------------|

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|             |       |
|-------------|-------|
| Lab Test ID | HMT13 |
|-------------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (22)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | PLATELETS                             |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 176                                   |
| Reported Numeric Result           | 176                                   |
| 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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (22)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

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Clinically Significant?

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Comment

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (23)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

---

|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W715942 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 08 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:10 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

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|            |        |
|------------|--------|
| Battery ID | HM1604 |
|------------|--------|

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|              |                                   |
|--------------|-----------------------------------|
| Battery Name | HEMATOLOGY<br>&DIFFERENTIAL PANEL |
|--------------|-----------------------------------|

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|             |       |
|-------------|-------|
| Lab Test ID | HMT15 |
|-------------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (23)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | NEUTROPHILS (%)                       |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 34.5                                  |
| Reported Numeric Result           | 34.5                                  |
| 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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (23)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

Low ☒

Clinically Significant?

No ☒

Comment

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (24)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

---

|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

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|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W715942 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 08 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:10 |
|------------------------|-------|

---

|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

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|            |        |
|------------|--------|
| Battery ID | HM1604 |
|------------|--------|

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|              |                                   |
|--------------|-----------------------------------|
| Battery Name | HEMATOLOGY<br>&DIFFERENTIAL PANEL |
|--------------|-----------------------------------|

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|             |       |
|-------------|-------|
| Lab Test ID | HMT16 |
|-------------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (24)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | LYMPHOCYTES (%)                       |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 56.0                                  |
| Reported Numeric Result           | 56.0                                  |
| 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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (24)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Numeric Result

---

---

SI Reference Range Low

---

---

SI Reference Range High

---

---

SI Units

---

---

Reported Result Type

---

---

Alert Flag

High ☒

---

Clinically Significant?

No ☒

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Comment

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (25)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

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|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

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|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W715942 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 08 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:10 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

---

|            |        |
|------------|--------|
| Battery ID | HM1604 |
|------------|--------|

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|              |                                   |
|--------------|-----------------------------------|
| Battery Name | HEMATOLOGY<br>&DIFFERENTIAL PANEL |
|--------------|-----------------------------------|

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|             |       |
|-------------|-------|
| Lab Test ID | HMT17 |
|-------------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (25)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |  |
|-----------------------------------|--|
| Lab Test Name                     | MONOCYTES (%)                            |
| Test ID                           |  |
| Test Status                       | Done <input checked="" type="checkbox"/> |
| Reported Text Result              | 5.4                                      |
| Reported Numeric Result           | 5.4                                      |
| 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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (25)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (26)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

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|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

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|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W715942 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 08 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:10 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

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|            |        |
|------------|--------|
| Battery ID | HM1604 |
|------------|--------|

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|              |                                   |
|--------------|-----------------------------------|
| Battery Name | HEMATOLOGY<br>&DIFFERENTIAL PANEL |
|--------------|-----------------------------------|

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|             |       |
|-------------|-------|
| Lab Test ID | HMT18 |
|-------------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (26)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | EOSINOPHILS (%)                       |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 3.7                                   |
| Reported Numeric Result           | 3.7                                   |
| 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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (26)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

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Alert Flag

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Clinically Significant?

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Comment

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (27)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

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|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

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|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

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|              |         |
|--------------|---------|
| Accession ID | W715942 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 08 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:10 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

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|            |        |
|------------|--------|
| Battery ID | HM1604 |
|------------|--------|

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|              |                                   |
|--------------|-----------------------------------|
| Battery Name | HEMATOLOGY<br>&DIFFERENTIAL PANEL |
|--------------|-----------------------------------|

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|             |       |
|-------------|-------|
| Lab Test ID | HMT19 |
|-------------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (27)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | BASOPHILS (%)                         |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 0.4                                   |
| Reported Numeric Result           | 0.4                                   |
| 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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (27)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

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Clinically Significant?

---

Comment

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (28)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

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|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

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|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W715942 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 08 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:10 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

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|            |        |
|------------|--------|
| Battery ID | HM1604 |
|------------|--------|

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|              |                                   |
|--------------|-----------------------------------|
| Battery Name | HEMATOLOGY<br>&DIFFERENTIAL PANEL |
|--------------|-----------------------------------|

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|             |      |
|-------------|------|
| Lab Test ID | HMT2 |
|-------------|------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (28)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | HEMATOCRIT                            |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 41                                    |
| Reported Numeric Result           | 41                                    |
| Reference Range low               | 39                                    |
| Reference Range high              | 54                                    |
| 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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (28)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (29)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

---

|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W715942 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 08 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:10 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

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|            |        |
|------------|--------|
| Battery ID | HM1604 |
|------------|--------|

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|              |                                   |
|--------------|-----------------------------------|
| Battery Name | HEMATOLOGY<br>&DIFFERENTIAL PANEL |
|--------------|-----------------------------------|

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|             |      |
|-------------|------|
| Lab Test ID | HMT3 |
|-------------|------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (29)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | RBC                                   |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 4.5                                   |
| Reported Numeric Result           | 4.5                                   |
| Reference Range low               | 4.5                                   |
| Reference Range high              | 6.4                                   |
| 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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (29)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (30)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

---

|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W715942 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 08 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:10 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

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|            |        |
|------------|--------|
| Battery ID | HM1604 |
|------------|--------|

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|              |                                   |
|--------------|-----------------------------------|
| Battery Name | HEMATOLOGY<br>&DIFFERENTIAL PANEL |
|--------------|-----------------------------------|

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|             |      |
|-------------|------|
| Lab Test ID | HMT4 |
|-------------|------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (30)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                               |
|-----------------------------------|-------------------------------|
| Lab Test Name                     | MCV                           |
| Test ID                           |                               |
| Test Status                       | Done <input type="checkbox"/> |
| Reported Text Result              | 92                            |
| Reported Numeric Result           | 92                            |
| Reference Range low               | 79                            |
| Reference Range high              | 96                            |
| 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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (30)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (31)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

---

|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W715942 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 08 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:10 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

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|            |        |
|------------|--------|
| Battery ID | HM1604 |
|------------|--------|

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|              |                                   |
|--------------|-----------------------------------|
| Battery Name | HEMATOLOGY<br>&DIFFERENTIAL PANEL |
|--------------|-----------------------------------|

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|             |       |
|-------------|-------|
| Lab Test ID | HMT40 |
|-------------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (31)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | HEMOGLOBIN                            |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 14.2                                  |
| Reported Numeric Result           | 14.2                                  |
| Reference Range low               | 12.7                                  |
| Reference Range high              | 18.1                                  |
| 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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (31)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (32)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

---

|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

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|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W715942 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 08 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:10 |
|------------------------|-------|

---

|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

---

|            |        |
|------------|--------|
| Battery ID | HM1604 |
|------------|--------|

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|              |                                   |
|--------------|-----------------------------------|
| Battery Name | HEMATOLOGY<br>&DIFFERENTIAL PANEL |
|--------------|-----------------------------------|

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|             |      |
|-------------|------|
| Lab Test ID | HMT7 |
|-------------|------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (32)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | WBC                                   |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 5.78                                  |
| Reported Numeric Result           | 5.78                                  |
| 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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (32)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (33)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

---

|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

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|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W715942 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 08 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:10 |
|------------------------|-------|

---

|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

---

|            |        |
|------------|--------|
| Battery ID | HM1604 |
|------------|--------|

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|              |                                   |
|--------------|-----------------------------------|
| Battery Name | HEMATOLOGY<br>&DIFFERENTIAL PANEL |
|--------------|-----------------------------------|

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|             |       |
|-------------|-------|
| Lab Test ID | HMT71 |
|-------------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (33)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (33)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (34)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

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|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

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|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W715942 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 08 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:10 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

---

|            |        |
|------------|--------|
| Battery ID | HM1604 |
|------------|--------|

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|              |                                   |
|--------------|-----------------------------------|
| Battery Name | HEMATOLOGY<br>&DIFFERENTIAL PANEL |
|--------------|-----------------------------------|

---

|             |      |
|-------------|------|
| Lab Test ID | HMT8 |
|-------------|------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (34)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | NEUTROPHILS                           |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 1.99                                  |
| Reported Numeric Result           | 1.99                                  |
| 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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (34)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (35)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

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|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

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|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W715942 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 08 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:10 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

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|            |        |
|------------|--------|
| Battery ID | HM1604 |
|------------|--------|

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|              |                                   |
|--------------|-----------------------------------|
| Battery Name | HEMATOLOGY<br>&DIFFERENTIAL PANEL |
|--------------|-----------------------------------|

---

|             |      |
|-------------|------|
| Lab Test ID | HMT9 |
|-------------|------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (35)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | LYMPHOCYTES                           |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 3.24                                  |
| Reported Numeric Result           | 3.24                                  |
| 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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (35)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (36)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

---

|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W715942 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 08 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:10 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

---

|            |        |
|------------|--------|
| Battery ID | UA1538 |
|------------|--------|

---

|              |                   |
|--------------|-------------------|
| Battery Name | URINE MACRO PANEL |
|--------------|-------------------|

---

|             |       |
|-------------|-------|
| Lab Test ID | UAT10 |
|-------------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (36)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (36)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (37)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

---

|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

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|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W715942 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 08 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:10 |
|------------------------|-------|

---

|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

---

|            |        |
|------------|--------|
| Battery ID | UA1538 |
|------------|--------|

---

|              |                   |
|--------------|-------------------|
| Battery Name | URINE MACRO PANEL |
|--------------|-------------------|

---

|             |      |
|-------------|------|
| Lab Test ID | UAT2 |
|-------------|------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (37)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | UR SPECIFIC GRAVITY                   |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 1.018                                 |
| Reported Numeric Result           | 1.018                                 |
| 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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (37)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (38)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

---

|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W715942 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 08 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:10 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

---

|            |        |
|------------|--------|
| Battery ID | UA1538 |
|------------|--------|

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|              |                   |
|--------------|-------------------|
| Battery Name | URINE MACRO PANEL |
|--------------|-------------------|

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|             |      |
|-------------|------|
| Lab Test ID | UAT3 |
|-------------|------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (38)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                               |
|-----------------------------------|-------------------------------|
| Lab Test Name                     | UR PH                         |
| Test ID                           |                               |
| Test Status                       | Done <input type="checkbox"/> |
| Reported Text Result              | 5.5                           |
| Reported Numeric Result           | 5.5                           |
| 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                    |                               |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (38)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (39)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

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|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

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|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

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|              |         |
|--------------|---------|
| Accession ID | W715942 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 08 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:10 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

---

|            |        |
|------------|--------|
| Battery ID | UA1538 |
|------------|--------|

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|              |                   |
|--------------|-------------------|
| Battery Name | URINE MACRO PANEL |
|--------------|-------------------|

---

|             |       |
|-------------|-------|
| Lab Test ID | UAT43 |
|-------------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (39)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

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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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (39)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (40)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

---

|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

---

|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

---

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

---

|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W715942 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 08 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:10 |
|------------------------|-------|

---

|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

---

|            |        |
|------------|--------|
| Battery ID | UA1538 |
|------------|--------|

---

|              |                   |
|--------------|-------------------|
| Battery Name | URINE MACRO PANEL |
|--------------|-------------------|

---

|             |       |
|-------------|-------|
| Lab Test ID | UAT49 |
|-------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (40)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

Lab Test Name


UR PROTEIN

---

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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (40)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (41)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

---

|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

---

|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

---

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

---

|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W715942 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 08 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:10 |
|------------------------|-------|

---

|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

---

|            |        |
|------------|--------|
| Battery ID | UA1538 |
|------------|--------|

---

|              |                   |
|--------------|-------------------|
| Battery Name | URINE MACRO PANEL |
|--------------|-------------------|

---

|             |      |
|-------------|------|
| Lab Test ID | UAT5 |
|-------------|------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (41)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (41)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (42)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

---

|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

---

|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

---

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

---

|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W715942 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 08 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:10 |
|------------------------|-------|

---

|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

---

|            |        |
|------------|--------|
| Battery ID | UA1538 |
|------------|--------|

---

|              |                   |
|--------------|-------------------|
| Battery Name | URINE MACRO PANEL |
|--------------|-------------------|

---

|             |      |
|-------------|------|
| Lab Test ID | UAT7 |
|-------------|------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (42)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_CCLS (42)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Oxysterol results (1)**

**Generated On: 20 Jul 2016 16:57:04**

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|                         |            |
|-------------------------|------------|
| Sample Accession number | 3271594239 |
|-------------------------|------------|

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|         |                              |
|---------|------------------------------|
| Analyte | 22(R)-HYDROXYCHOLESTERO<br>L |
|---------|------------------------------|

---

|              |         |
|--------------|---------|
| Analyte code | 22RHCRL |
|--------------|---------|

---

|        |  |
|--------|--|
| Result |  |
|--------|--|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|         |  |
|---------|--|
| Comment | NOT ANALYSED, INCOMPLETE<br>SAMPLE SET |
|---------|--|

---

|                               |      |
|-------------------------------|------|
| Lower limit of quantification | 9.46 |
|-------------------------------|------|

---

|                                   |  |
|-----------------------------------|--|
| Date of Collection<br>DD MMM YYYY |  |
|-----------------------------------|--|

---

|  |  |
|--|--|
| Collection time<br>hh:mm 24 hour clock |  |
|--|--|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Oxysterol results (2)**

**Generated On: 20 Jul 2016 16:57:04**

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|                         |            |
|-------------------------|------------|
| Sample Accession number | 3271594239 |
|-------------------------|------------|

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|         |                              |
|---------|------------------------------|
| Analyte | 24(R)-HYDROXYCHOLESTERO<br>L |
|---------|------------------------------|

---

|              |         |
|--------------|---------|
| Analyte code | 24RHCRL |
|--------------|---------|

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|        |  |
|--------|--|
| Result |  |
|--------|--|

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|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|         |  |
|---------|--|
| Comment | NOT ANALYSED, INCOMPLETE<br>SAMPLE SET |
|---------|--|

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|                               |      |
|-------------------------------|------|
| Lower limit of quantification | 6.56 |
|-------------------------------|------|

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|                                   |  |
|-----------------------------------|--|
| Date of Collection<br>DD MMM YYYY |  |
|-----------------------------------|--|

---

|  |  |
|--|--|
| Collection time<br>hh:mm 24 hour clock |  |
|--|--|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Oxysterol results (3)**

**Generated On: 20 Jul 2016 16:57:04**

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|                         |            |
|-------------------------|------------|
| Sample Accession number | 3271594239 |
|-------------------------|------------|

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|         |                       |
|---------|-----------------------|
| Analyte | 25-HYDROXYCHOLESTEROL |
|---------|-----------------------|

---

|              |        |
|--------------|--------|
| Analyte code | 25HCRL |
|--------------|--------|

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|        |  |
|--------|--|
| Result |  |
|--------|--|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|         |  |
|---------|--|
| Comment | NOT ANALYSED, INCOMPLETE<br>SAMPLE SET |
|---------|--|

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|                               |      |
|-------------------------------|------|
| Lower limit of quantification | 4.70 |
|-------------------------------|------|

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|                                   |  |
|-----------------------------------|--|
| Date of Collection<br>DD MMM YYYY |  |
|-----------------------------------|--|

---

|  |  |
|--|--|
| Collection time<br>hh:mm 24 hour clock |  |
|--|--|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Oxysterol results (4)**

**Generated On: 20 Jul 2016 16:57:04**

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|                         |            |
|-------------------------|------------|
| Sample Accession number | 3271594239 |
|-------------------------|------------|

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|         |                       |
|---------|-----------------------|
| Analyte | 27-HYDROXYCHOLESTEROL |
|---------|-----------------------|

---

|              |        |
|--------------|--------|
| Analyte code | 27HCRL |
|--------------|--------|

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|        |  |
|--------|--|
| Result |  |
|--------|--|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|         |  |
|---------|--|
| Comment | NOT ANALYSED, INCOMPLETE<br>SAMPLE SET |
|---------|--|

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|                               |       |
|-------------------------------|-------|
| Lower limit of quantification | 11.60 |
|-------------------------------|-------|

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|                                   |  |
|-----------------------------------|--|
| Date of Collection<br>DD MMM YYYY |  |
|-----------------------------------|--|

---

|  |  |
|--|--|
| Collection time<br>hh:mm 24 hour clock |  |
|--|--|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Oxysterol results (5)**

**Generated On: 20 Jul 2016 16:57:04**

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|                         |            |
|-------------------------|------------|
| Sample Accession number | 3271594239 |
|-------------------------|------------|

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|         |                       |
|---------|-----------------------|
| Analyte | 4B-HYDROXYCHOLESTEROL |
|---------|-----------------------|

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|              |        |
|--------------|--------|
| Analyte code | 4BHCRL |
|--------------|--------|

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|        |  |
|--------|--|
| Result |  |
|--------|--|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

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|         |  |
|---------|--|
| Comment | NOT ANALYSED, INCOMPLETE<br>SAMPLE SET |
|---------|--|

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|                               |       |
|-------------------------------|-------|
| Lower limit of quantification | 10.66 |
|-------------------------------|-------|

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|                                   |  |
|-----------------------------------|--|
| Date of Collection<br>DD MMM YYYY |  |
|-----------------------------------|--|

---

|  |  |
|--|--|
| Collection time<br>hh:mm 24 hour clock |  |
|--|--|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Oxysterol results (6)**

**Generated On: 20 Jul 2016 16:57:04**

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|                         |            |
|-------------------------|------------|
| Sample Accession number | 3271594239 |
|-------------------------|------------|

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|         |                        |
|---------|------------------------|
| Analyte | 5A,6A-EPOXYCHOLESTANOL |
|---------|------------------------|

---

|              |          |
|--------------|----------|
| Analyte code | 5A6AECNL |
|--------------|----------|

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|        |  |
|--------|--|
| Result |  |
|--------|--|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|         |  |
|---------|--|
| Comment | NOT ANALYSED, INCOMPLETE<br>SAMPLE SET |
|---------|--|

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|                               |       |
|-------------------------------|-------|
| Lower limit of quantification | 12.46 |
|-------------------------------|-------|

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|                                   |  |
|-----------------------------------|--|
| Date of Collection<br>DD MMM YYYY |  |
|-----------------------------------|--|

---

|  |  |
|--|--|
| Collection time<br>hh:mm 24 hour clock |  |
|--|--|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Oxysterol results (7)**

**Generated On: 20 Jul 2016 16:57:04**

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|                         |            |
|-------------------------|------------|
| Sample Accession number | 3271594239 |
|-------------------------|------------|

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|         |                        |
|---------|------------------------|
| Analyte | 5B,6B-EPOXYCHOLESTANOL |
|---------|------------------------|

---

|              |          |
|--------------|----------|
| Analyte code | 5B6BECNL |
|--------------|----------|

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|        |  |
|--------|--|
| Result |  |
|--------|--|

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|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

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|         |  |
|---------|--|
| Comment | NOT ANALYSED, INCOMPLETE<br>SAMPLE SET |
|---------|--|

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|                               |       |
|-------------------------------|-------|
| Lower limit of quantification | 26.83 |
|-------------------------------|-------|

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|                                   |  |
|-----------------------------------|--|
| Date of Collection<br>DD MMM YYYY |  |
|-----------------------------------|--|

---

|  |  |
|--|--|
| Collection time<br>hh:mm 24 hour clock |  |
|--|--|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Oxysterol results (8)**

**Generated On: 20 Jul 2016 16:57:04**

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|                         |            |
|-------------------------|------------|
| Sample Accession number | 3271594239 |
|-------------------------|------------|

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|         |                               |
|---------|-------------------------------|
| Analyte | 6A-HYDROXY-5A-CHOLESTAN<br>OL |
|---------|-------------------------------|

---

|              |          |
|--------------|----------|
| Analyte code | 6AH5ACNL |
|--------------|----------|

---

|        |  |
|--------|--|
| Result |  |
|--------|--|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|         |  |
|---------|--|
| Comment | NOT ANALYSED, INCOMPLETE<br>SAMPLE SET |
|---------|--|

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|                               |       |
|-------------------------------|-------|
| Lower limit of quantification | 13.70 |
|-------------------------------|-------|

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|                                   |  |
|-----------------------------------|--|
| Date of Collection<br>DD MMM YYYY |  |
|-----------------------------------|--|

---

|  |  |
|--|--|
| Collection time<br>hh:mm 24 hour clock |  |
|--|--|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Oxysterol results (9)**

**Generated On: 20 Jul 2016 16:57:04**

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|                         |            |
|-------------------------|------------|
| Sample Accession number | 3271594239 |
|-------------------------|------------|

---

|         |                   |
|---------|-------------------|
| Analyte | 7-KETOCHOLESTEROL |
|---------|-------------------|

---

|              |       |
|--------------|-------|
| Analyte code | 7KCRL |
|--------------|-------|

---

|        |  |
|--------|--|
| Result |  |
|--------|--|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|         |  |
|---------|--|
| Comment | NOT ANALYSED, INCOMPLETE<br>SAMPLE SET |
|---------|--|

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|                               |       |
|-------------------------------|-------|
| Lower limit of quantification | 15.43 |
|-------------------------------|-------|

---

|                                   |  |
|-----------------------------------|--|
| Date of Collection<br>DD MMM YYYY |  |
|-----------------------------------|--|

---

|  |  |
|--|--|
| Collection time<br>hh:mm 24 hour clock |  |
|--|--|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Oxysterol results (10)**

**Generated On: 20 Jul 2016 16:57:04**

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|                         |            |
|-------------------------|------------|
| Sample Accession number | 3271594239 |
|-------------------------|------------|

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|         |                       |
|---------|-----------------------|
| Analyte | 7A-HYDROXYCHOLESTEROL |
|---------|-----------------------|

---

|              |        |
|--------------|--------|
| Analyte code | 7AHCRL |
|--------------|--------|

---

|        |  |
|--------|--|
| Result |  |
|--------|--|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|         |  |
|---------|--|
| Comment | NOT ANALYSED, INCOMPLETE<br>SAMPLE SET |
|---------|--|

---

|                               |       |
|-------------------------------|-------|
| Lower limit of quantification | 13.46 |
|-------------------------------|-------|

---

|                                   |  |
|-----------------------------------|--|
| Date of Collection<br>DD MMM YYYY |  |
|-----------------------------------|--|

---

|  |  |
|--|--|
| Collection time<br>hh:mm 24 hour clock |  |
|--|--|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Oxysterol results (11)**

**Generated On: 20 Jul 2016 16:57:04**

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|                         |            |
|-------------------------|------------|
| Sample Accession number | 3271594239 |
|-------------------------|------------|

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|         |                       |
|---------|-----------------------|
| Analyte | 7B-HYDROXYCHOLESTEROL |
|---------|-----------------------|

---

|              |        |
|--------------|--------|
| Analyte code | 7BHCRL |
|--------------|--------|

---

|        |  |
|--------|--|
| Result |  |
|--------|--|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|         |  |
|---------|--|
| Comment | NOT ANALYSED, INCOMPLETE<br>SAMPLE SET |
|---------|--|

---

|                               |       |
|-------------------------------|-------|
| Lower limit of quantification | 12.86 |
|-------------------------------|-------|

---

|                                   |  |
|-----------------------------------|--|
| Date of Collection<br>DD MMM YYYY |  |
|-----------------------------------|--|

---

|  |  |
|--|--|
| Collection time<br>hh:mm 24 hour clock |  |
|--|--|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Oxysterol results (12)**

**Generated On: 20 Jul 2016 16:57:04**

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|                         |            |
|-------------------------|------------|
| Sample Accession number | 3271594239 |
|-------------------------|------------|

---

|         |             |
|---------|-------------|
| Analyte | CHOLESTEROL |
|---------|-------------|

---

|              |      |
|--------------|------|
| Analyte code | CHOL |
|--------------|------|

---

|        |  |
|--------|--|
| Result |  |
|--------|--|

---

|             |       |
|-------------|-------|
| Result Unit | MG/ML |
|-------------|-------|

---

|         |  |
|---------|--|
| Comment | NOT ANALYSED, INCOMPLETE<br>SAMPLE SET |
|---------|--|

---

|                               |      |
|-------------------------------|------|
| Lower limit of quantification | 0.50 |
|-------------------------------|------|

---

|                                   |  |
|-----------------------------------|--|
| Date of Collection<br>DD MMM YYYY |  |
|-----------------------------------|--|

---

|  |  |
|--|--|
| Collection time<br>hh:mm 24 hour clock |  |
|--|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_COHB (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:45**

**Generated On: 20 Jul 2016 16:57:04**

|                               |                    |
|-------------------------------|--------------------|
| Sample Barcode                | 05115150001266     |
| Analyte                       | CARBOXYHEMOGLOBIN  |
| Sample type                   | BLOOD              |
| Result                        | 3.70               |
| Result Unit                   | %                  |
| Lab Status                    | OK                 |
| Sample comment                | .                  |
| 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-MAR-08        |
| Timepoint-minutes             |                    |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_COHB (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:45**

**Generated On: 20 Jul 2016 16:57:04**

---

Start Day (24 hour urine only) \_\_\_\_\_

---

End Day (24 hour Urine Only) \_\_\_\_\_

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_COHB (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:45**

**Generated On: 20 Jul 2016 16:57:04**

|                               |                    |
|-------------------------------|--------------------|
| Sample Barcode                | 05115150001267     |
| Analyte                       | CARBOXYHEMOGLOBIN  |
| Sample type                   | BLOOD              |
| Result                        | 5.30               |
| Result Unit                   | %                  |
| Lab Status                    | OK                 |
| Sample comment                | .                  |
| 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-MAR-08        |
| Timepoint-minutes             |                    |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Lab\_BU\_COHB (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:45**

**Generated On: 20 Jul 2016 16:57:04**

---

Start Day (24 hour urine only) \_\_\_\_\_

---

End Day (24 hour Urine Only) \_\_\_\_\_

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:39**

**Generated On: 20 Jul 2016 16:57:04**

---

Date of Birth

(b) (6)

---

Date of assessment

2014 MAR 08

DD/MMM/YYYY

DD/MMM/YYYY

---

Time of assessment

20:03

hour:min 24-hour clock

---

Assessment Status

Completed

---

1. Was smoking satisfying?

A lot

---

2. Did cigarettes taste good?

Very little

---

3. Did you enjoy the sensation in your throat and chest?

Moderately

---

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?

Very little

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:39**

**Generated On: 20 Jul 2016 16:57:04**

---

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? Quite a lot ☐

---

12. Did you enjoy smoking? Very little ☐

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Human Smoking Topography Questionnaire**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

|      |  |
|------|--|
| Type | HUMAN SMOKING<br>TOPOGRAPHY<br>QUESTIONNAIRE |
|------|--|

---

|                               |                           |
|-------------------------------|---------------------------|
| Was paper questionnaire used? | Yes <input type="radio"/> |
|-------------------------------|---------------------------|

---

|                 |  |
|-----------------|--|
| Reason not done |  |
|-----------------|--|

---

|                    |                            |
|--------------------|----------------------------|
| Date of assessment | 08 MAR 2014<br>DD/MMM/YYYY |
|--------------------|----------------------------|

---

|                    |                                 |
|--------------------|---------------------------------|
| Time of assessment | 20:50<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 agree <input type="radio"/> |
|--|--------------------------------------|

---

|   |   |
|---|---|
| If you agree or strongly agree, please describe : | IT IS CUMBERSOME ND<br>DOESN'T ALWAYS WORK<br>PROPERLY. |
|---|---|

---

|   |                                |
|---|--------------------------------|
| 2. You enjoy smoking with the device as much as without it. | Disagree <input type="radio"/> |
|---|--------------------------------|

---

|   |                                 |
|---|---------------------------------|
| If you disagree or strongly disagree, please describe : | I COULD DO WITH THAT<br>DEVICE. |
|---|---------------------------------|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Human Smoking Topography Questionnaire**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:25**

**Generated On: 20 Jul 2016 16:57:04**

---

3. The taste of the conventional cigarettes/products is different with the device.

Agree ☒

---

If you agree or strongly agree, please describe :

IT TAKES A LOT OF THE FLAVOR AWAY.

---

4. The device is easy to use.

Neither agree nor disagree ☐

---

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 :

TIME CONSUMING. IT'S EASIER TO JUST LIGHT UP AND SMOKE WITHOUT IT.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Questionnaire on smoking urges (QSU)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:40**

**Generated On: 20 Jul 2016 16:57:04**

|   |   |
|---|---|
| Type  | QSU                                     |
| Date of Birth   | (b) (6)                                 |
| Date of assessment<br>DD/MMM/YYYY                             | 2014 MAR 08                             |
| Time of assessment<br>hour:min 24-hour clock                  | 20:02                                   |
| Assessment Status   | Completed <input type="radio"/>         |
| 1. I have a desire for a cigarette right now                  | Strongly disagree <input type="radio"/> |
| 2. Nothing would be better than smoking a cigarette right now | Strongly disagree <input type="radio"/> |
| 3. If it were possible I would probably smoke now             | Strongly 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                        | Strongly disagree <input type="radio"/> |
| 6. I have an urge for a cigarette                             | Strongly disagree <input type="radio"/> |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Questionnaire on smoking urges (QSU)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:40**

**Generated On: 20 Jul 2016 16:57:04**

---

7. A cigarette would taste good now Strongly disagree ☐

---

8. I would do almost anything for a cigarette now Strongly disagree ☐

---

9. Smoking would make me less depressed Strongly disagree ☐

---

10. I am going to smoke as soon as possible Strongly disagree ☐

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:41**

**Generated On: 20 Jul 2016 16:57:04**

---

|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

---

|                      |      |
|----------------------|------|
| Subject ID or Number | 1194 |
|----------------------|------|

---

|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

---

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

---

|            |      |
|------------|------|
| Visit Name | DAY0 |
|------------|------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W715942 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 08 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:10 |
|------------------------|-------|

---

|                    |  |
|--------------------|--|
| Specimen Condition |  |
|--------------------|--|

---

|            |        |
|------------|--------|
| Battery ID | HM1054 |
|------------|--------|

---

|              |                |
|--------------|----------------|
| Battery Name | HEMOGLOBIN A1C |
|--------------|----------------|

---

|             |        |
|-------------|--------|
| Lab Test ID | HMT370 |
|-------------|--------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:41**

**Generated On: 20 Jul 2016 16:57:04**

---

Lab Test Name


HEMOGLOBIN  
A1C,VARIANT(-70)

---

Test ID

---

Test Status

Done 

---

Reported Text Result

5.8

---

Reported Numeric Result

5.8

---

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: 1194**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:41**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:41**

**Generated On: 20 Jul 2016 16:57:04**

---

|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

---

|                      |      |
|----------------------|------|
| Subject ID or Number | 1194 |
|----------------------|------|

---

|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

---

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

---

|            |      |
|------------|------|
| Visit Name | DAY0 |
|------------|------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W715942 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 08 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:10 |
|------------------------|-------|

---

|                    |  |
|--------------------|--|
| Specimen Condition |  |
|--------------------|--|

---

|            |        |
|------------|--------|
| Battery ID | RC6871 |
|------------|--------|

---

|              |     |
|--------------|-----|
| Battery Name | HDL |
|--------------|-----|

---

|             |         |
|-------------|---------|
| Lab Test ID | RCT1684 |
|-------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:41**

**Generated On: 20 Jul 2016 16:57:04**

---

Lab Test Name

DIRECT HDL-C 3RD  
GENERATION


---

Test ID

---

---

Test Status

Done 

---

Reported Text Result

54

---

Reported Numeric Result

54

---

Reference Range low

28

---

Reference Range high

63

---

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: 1194**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:41**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:41**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

---

|                      |      |
|----------------------|------|
| Subject ID or Number | 1194 |
|----------------------|------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

---

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

---

|            |      |
|------------|------|
| Visit Name | DAY0 |
|------------|------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W715942 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 08 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:10 |
|------------------------|-------|

---

|                    |  |
|--------------------|--|
| Specimen Condition |  |
|--------------------|--|

---

|            |        |
|------------|--------|
| Battery ID | SC3249 |
|------------|--------|

---

|              |        |
|--------------|--------|
| Battery Name | HS-CRP |
|--------------|--------|

---

|             |         |
|-------------|---------|
| Lab Test ID | SCT1528 |
|-------------|---------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:41**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | C-REACTIVE PROTEIN (NHS)-QT           |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 0.073                                 |
| Reported Numeric Result           | 0.073                                 |
| 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: 1194**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:41**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:41**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

---

|                      |      |
|----------------------|------|
| Subject ID or Number | 1194 |
|----------------------|------|

---

|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

---

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

---

|            |      |
|------------|------|
| Visit Name | DAY0 |
|------------|------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W715942 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 08 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:10 |
|------------------------|-------|

---

|                    |  |
|--------------------|--|
| Specimen Condition |  |
|--------------------|--|

---

|            |        |
|------------|--------|
| Battery ID | SC3582 |
|------------|--------|

---

|              |                |
|--------------|----------------|
| Battery Name | APOLIPOPROTEIN |
|--------------|----------------|

---

|             |         |
|-------------|---------|
| Lab Test ID | SCT3639 |
|-------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:41**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | APOLIPOPROTEIN A1, RAND               |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 139                                   |
| Reported Numeric Result           | 139                                   |
| Reference Range low               | 110                                   |
| Reference Range high              | 205                                   |
| 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: 1194**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:41**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (5)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:41**

**Generated On: 20 Jul 2016 16:57:04**

---

|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

---

|                      |      |
|----------------------|------|
| Subject ID or Number | 1194 |
|----------------------|------|

---

|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

---

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

---

|            |      |
|------------|------|
| Visit Name | DAY0 |
|------------|------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W715942 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 08 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:10 |
|------------------------|-------|

---

|                    |  |
|--------------------|--|
| Specimen Condition |  |
|--------------------|--|

---

|            |        |
|------------|--------|
| Battery ID | SC3582 |
|------------|--------|

---

|              |                |
|--------------|----------------|
| Battery Name | APOLIPOPROTEIN |
|--------------|----------------|

---

|             |         |
|-------------|---------|
| Lab Test ID | SCT3643 |
|-------------|---------|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (5)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:41**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | APOLIPOPROTEIN B, RAND                |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 49                                    |
| Reported Numeric Result           | 49                                    |
| Reference Range low               | 55                                    |
| Reference Range high              | 140                                   |
| 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: 1194**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (5)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:41**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

Low 

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (6)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:41**

**Generated On: 20 Jul 2016 16:57:04**

---

|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

---

|                      |      |
|----------------------|------|
| Subject ID or Number | 1194 |
|----------------------|------|

---

|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

---

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

---

|            |      |
|------------|------|
| Visit Name | DAY0 |
|------------|------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W715942 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 08 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:10 |
|------------------------|-------|

---

|                    |  |
|--------------------|--|
| Specimen Condition |  |
|--------------------|--|

---

|            |       |
|------------|-------|
| Battery ID | CG267 |
|------------|-------|

---

|              |            |
|--------------|------------|
| Battery Name | FIBRINOGEN |
|--------------|------------|

---

|             |        |
|-------------|--------|
| Lab Test ID | CGT285 |
|-------------|--------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (6)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:41**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | FIBRINOGEN                            |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 271                                   |
| Reported Numeric Result           | 271                                   |
| 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: 1194**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (6)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:41**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (7)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:41**

**Generated On: 20 Jul 2016 16:57:04**

---

|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

---

|                      |      |
|----------------------|------|
| Subject ID or Number | 1194 |
|----------------------|------|

---

|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

---

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

---

|            |      |
|------------|------|
| Visit Name | DAY0 |
|------------|------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W715942 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 08 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:10 |
|------------------------|-------|

---

|                    |  |
|--------------------|--|
| Specimen Condition |  |
|--------------------|--|

---

|            |       |
|------------|-------|
| Battery ID | CN236 |
|------------|-------|

---

|              |              |
|--------------|--------------|
| Battery Name | HOMOCYSTEINE |
|--------------|--------------|

---

|             |        |
|-------------|--------|
| Lab Test ID | CNT145 |
|-------------|--------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (7)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:41**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | HOMOCYSTEINE, EDTAPL                  |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 10.26                                 |
| Reported Numeric Result           | 10.26                                 |
| 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: 1194**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (7)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:41**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (8)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:41**

**Generated On: 20 Jul 2016 16:57:04**

---

|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

---

|                      |      |
|----------------------|------|
| Subject ID or Number | 1194 |
|----------------------|------|

---

|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

---

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

---

|            |      |
|------------|------|
| Visit Name | DAY0 |
|------------|------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W715942 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 08 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:10 |
|------------------------|-------|

---

|                    |  |
|--------------------|--|
| Specimen Condition |  |
|--------------------|--|

---

|            |        |
|------------|--------|
| Battery ID | IM2293 |
|------------|--------|

---

|              |         |
|--------------|---------|
| Battery Name | SICAM-1 |
|--------------|---------|

---

|             |         |
|-------------|---------|
| Lab Test ID | IMT1768 |
|-------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (8)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:41**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | SICAM-1-RUO                           |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 210.1                                 |
| Reported Numeric Result           | 210.1                                 |
| 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: 1194**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (8)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:41**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (9)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:41**

**Generated On: 20 Jul 2016 16:57:04**

---

|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

---

|                      |      |
|----------------------|------|
| Subject ID or Number | 1194 |
|----------------------|------|

---

|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

---

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

---

|            |      |
|------------|------|
| Visit Name | DAY0 |
|------------|------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W715942 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 08 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:10 |
|------------------------|-------|

---

|                    |  |
|--------------------|--|
| Specimen Condition |  |
|--------------------|--|

---

|            |        |
|------------|--------|
| Battery ID | RC9267 |
|------------|--------|

---

|              |     |
|--------------|-----|
| Battery Name | LDL |
|--------------|-----|

---

|             |         |
|-------------|---------|
| Lab Test ID | RCT2394 |
|-------------|---------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (9)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:41**

**Generated On: 20 Jul 2016 16:57:04**

---

|               |                            |
|---------------|----------------------------|
| Lab Test Name | DIRECT LDL-C 2ND GEN (-70) |
|---------------|----------------------------|

---

|         |       |
|---------|-------|
| Test ID | <hr/> |
|---------|-------|

---

|             |                                       |
|-------------|---------------------------------------|
| Test Status | Done <input checked="" type="radio"/> |
|-------------|---------------------------------------|

---

|                      |    |
|----------------------|----|
| Reported Text Result | 72 |
|----------------------|----|

---

|                         |    |
|-------------------------|----|
| Reported Numeric Result | 72 |
|-------------------------|----|

---

|                     |    |
|---------------------|----|
| Reference Range low | 78 |
|---------------------|----|

---

|                      |     |
|----------------------|-----|
| Reference Range high | 185 |
|----------------------|-----|

---

|             |       |
|-------------|-------|
| 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: 1194**

**Folder: Baseline (Day 0)**

**Form: Risk Markers(CCLS) (9)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:41**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

Low 

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (CEMA, HPMa, HBMA)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:47**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:47**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112450002133    |
| Analyte                   | HPMA              |
| Sample type               | URINE             |
| Result                    | 468               |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 0                 |
| Celerion Study Number     | AA99128-03        |
| Date of Collection        | 2014-MAR-08       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 0                 |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:47**

**Generated On: 20 Jul 2016 16:57:04**

---

|               |   |
|---------------|---|
| Urine End Day | 1 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:47**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112450002133    |
| Analyte                   | CEMA              |
| Sample type               | URINE             |
| Result                    | 55.4              |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 0                 |
| Celerion Study Number     | AA99128-03        |
| Date of Collection        | 2014-MAR-08       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 0                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:47**

**Generated On: 20 Jul 2016 16:57:04**

---

|               |   |
|---------------|---|
| Urine End Day | 1 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (CEMA, HPMa, HBMA) (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:47**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112450002133    |
| Analyte                   | HBMA              |
| Sample type               | URINE             |
| Result                    | 293               |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 0                 |
| Celerion Study Number     | AA99128-03        |
| Date of Collection        | 2014-MAR-08       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 0                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:47**

**Generated On: 20 Jul 2016 16:57:04**

---

|               |   |
|---------------|---|
| Urine End Day | 1 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (NNN, NNAL)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:46**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (NNN, NNAL) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:46**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112460002544    |
| Analyte                   | NNAL              |
| Sample type               | URINE             |
| Result                    | 47.6              |
| Result Unit               | PG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 0                 |
| Celerion Study Number     | AA99128-04        |
| Date of Collection        | 2014-MAR-08       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 0                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (NNN, NNAL) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:46**

**Generated On: 20 Jul 2016 16:57:04**

---

|               |   |
|---------------|---|
| Urine End Day | 1 |
|---------------|---|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (NNN, NNAL) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:46**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112460002544    |
| Analyte                   | NNN               |
| Sample type               | URINE             |
| Result                    | 2.28              |
| Result Unit               | PG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 0                 |
| Celerion Study Number     | AA99128-04        |
| Date of Collection        | 2014-MAR-08       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 0                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (NNN, NNAL) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:46**

**Generated On: 20 Jul 2016 16:57:04**

---

|               |   |
|---------------|---|
| Urine End Day | 1 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (HEMA)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:46**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (HEMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:46**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112470001268    |
| Analyte                   | HEMA              |
| Sample type               | URINE             |
| Result                    | 3.56              |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 0                 |
| Celerion Study Number     | AA99128-05        |
| Date of Collection        | 2014-MAR-08       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 0                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (HEMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:46**

**Generated On: 20 Jul 2016 16:57:04**

---

|               |   |
|---------------|---|
| Urine End Day | 1 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:47**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:47**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112480000663    |
| Analyte                   | COT               |
| Sample type               | URINE             |
| Result                    | 1120              |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 0                 |
| Celerion Study Number     | AA99128-06        |
| Date of Collection        | 2014-MAR-09       |
| Timepoint-minutes         |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:47**

**Generated On: 20 Jul 2016 16:57:04**

---

|                 |   |
|-----------------|---|
| Urine Start Day | 0 |
| <hr/>           |   |
| Urine End Day   | 1 |
| <hr/>           |   |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:47**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112480000663    |
| Analyte                   | COT-GLUC          |
| Sample type               | URINE             |
| Result                    | 1240              |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 0                 |
| Celerion Study Number     | AA99128-06        |
| Date of Collection        | 2014-MAR-09       |
| Timepoint-minutes         |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:47**

**Generated On: 20 Jul 2016 16:57:04**

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|                 |   |
|-----------------|---|
| Urine Start Day | 0 |
| <hr/>           |   |
| Urine End Day   | 1 |
| <hr/>           |   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:47**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112480000663    |
| Analyte                   | NIC               |
| Sample type               | URINE             |
| Result                    | 215               |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 0                 |
| Celerion Study Number     | AA99128-06        |
| Date of Collection        | 2014-MAR-09       |
| Timepoint-minutes         |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:47**

**Generated On: 20 Jul 2016 16:57:04**

---

|                 |   |
|-----------------|---|
| Urine Start Day | 0 |
| <hr/>           |   |
| Urine End Day   | 1 |
| <hr/>           |   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:47**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112480000663    |
| Analyte                   | NIC-GLUC          |
| Sample type               | URINE             |
| Result                    | 265               |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 0                 |
| Celerion Study Number     | AA99128-06        |
| Date of Collection        | 2014-MAR-09       |
| Timepoint-minutes         |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:47**

**Generated On: 20 Jul 2016 16:57:04**

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|                 |   |
|-----------------|---|
| Urine Start Day | 0 |
| <hr/>           |   |
| Urine End Day   | 1 |
| <hr/>           |   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc) (5)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:47**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112480000663    |
| Analyte                   | THCOT             |
| Sample type               | URINE             |
| Result                    | 1120              |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 0                 |
| Celerion Study Number     | AA99128-06        |
| Date of Collection        | 2014-MAR-09       |
| Timepoint-minutes         |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(5)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:47**

**Generated On: 20 Jul 2016 16:57:04**

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|                 |   |
|-----------------|---|
| Urine Start Day | 0 |
| <hr/>           |   |
| Urine End Day   | 1 |
| <hr/>           |   |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc) (6)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:47**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112480000663    |
| Analyte                   | THCOT-GLUC        |
| Sample type               | URINE             |
| Result                    | 466               |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 0                 |
| Celerion Study Number     | AA99128-06        |
| Date of Collection        | 2014-MAR-09       |
| Timepoint-minutes         |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(6)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:47**

**Generated On: 20 Jul 2016 16:57:04**

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|                 |   |
|-----------------|---|
| Urine Start Day | 0 |
| <hr/>           |   |
| Urine End Day   | 1 |
| <hr/>           |   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (3-OH BaP)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:47**

**Generated On: 20 Jul 2016 16:57:04**

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Sample type

URINE

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (3-OH BaP) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:47**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112490001268    |
| Analyte                   | 3-OH BAP          |
| Sample type               | URINE             |
| Result                    | 33.2              |
| Result Unit               | FG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 0                 |
| Celerion Study Number     | AA99128-07        |
| Date of Collection        | 2014-MAR-08       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 0                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (3-OH BaP) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:47**

**Generated On: 20 Jul 2016 16:57:04**

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|               |   |
|---------------|---|
| Urine End Day | 1 |
|---------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Plasma (Caffeine, Paraxanthine)**

**Generated On: 20 Jul 2016 16:57:04**

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Sample type

PLASMA

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Plasma (Caffeine, Paraxanthine) (1)**

**Generated On: 20 Jul 2016 16:57:04**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05112500000346 |
|----------------|----------------|

---

|         |          |
|---------|----------|
| Analyte | CAFFEINE |
|---------|----------|

---

|             |        |
|-------------|--------|
| Sample type | PLASMA |
|-------------|--------|

---

|        |      |
|--------|------|
| Result | 1510 |
|--------|------|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

---

|                |                   |
|----------------|-------------------|
| Sample comment | ANALYZED IN ERROR |
|----------------|-------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 6 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 0 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-08 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-08 |
|--------------------|-------------|

---

|                   |   |
|-------------------|---|
| Timepoint-minutes | 0 |
|-------------------|---|

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|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Plasma (Caffeine, Paraxanthine) (1)**

**Generated On: 20 Jul 2016 16:57:04**

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|               |   |
|---------------|---|
| Urine End Day | 0 |
|---------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Plasma (Caffeine, Paraxanthine) (2)**

**Generated On: 20 Jul 2016 16:57:04**

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|                |                |
|----------------|----------------|
| Sample Barcode | 05112500000346 |
|----------------|----------------|

---

|         |              |
|---------|--------------|
| Analyte | PARAXANTHINE |
|---------|--------------|

---

|             |        |
|-------------|--------|
| Sample type | PLASMA |
|-------------|--------|

---

|        |      |
|--------|------|
| Result | 1270 |
|--------|------|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

---

|                |                   |
|----------------|-------------------|
| Sample comment | ANALYZED IN ERROR |
|----------------|-------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 6 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 0 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-08 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-08 |
|--------------------|-------------|

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|                   |   |
|-------------------|---|
| Timepoint-minutes | 0 |
|-------------------|---|

---

|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Plasma (Caffeine, Paraxanthine) (2)**

**Generated On: 20 Jul 2016 16:57:04**

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|               |   |
|---------------|---|
| Urine End Day | 0 |
|---------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:48**

**Generated On: 20 Jul 2016 16:57:04**

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Sample type

URINE

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:48**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112510001290    |
| Analyte                   | 1-NA              |
| Sample type               | URINE             |
| Result                    | 32.6              |
| Result Unit               | PG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 0                 |
| Celerion Study Number     | AA99128-09        |
| Date of Collection        | 2014-MAR-08       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 0                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:48**

**Generated On: 20 Jul 2016 16:57:04**

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|               |   |
|---------------|---|
| Urine End Day | 1 |
|---------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:48**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112510001290    |
| Analyte                   | 2-NA              |
| Sample type               | URINE             |
| Result                    | 7.60              |
| Result Unit               | PG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 0                 |
| Celerion Study Number     | AA99128-09        |
| Date of Collection        | 2014-MAR-08       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 0                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:48**

**Generated On: 20 Jul 2016 16:57:04**

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|               |   |
|---------------|---|
| Urine End Day | 1 |
|---------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:48**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112510001290    |
| Analyte                   | 4-ABP             |
| Sample type               | URINE             |
| Result                    | 5.21              |
| Result Unit               | PG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 0                 |
| Celerion Study Number     | AA99128-09        |
| Date of Collection        | 2014-MAR-08       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 0                 |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:48**

**Generated On: 20 Jul 2016 16:57:04**

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|               |   |
|---------------|---|
| Urine End Day | 1 |
|---------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:48**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112510001290    |
| Analyte                   | O-TOL             |
| Sample type               | URINE             |
| Result                    | BLQ<(50.0)        |
| Result Unit               | PG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 0                 |
| Celerion Study Number     | AA99128-09        |
| Date of Collection        | 2014-MAR-08       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 0                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:48**

**Generated On: 20 Jul 2016 16:57:04**

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|               |   |
|---------------|---|
| Urine End Day | 1 |
|---------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (11-dTXb2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:46**

**Generated On: 20 Jul 2016 16:57:04**

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Sample type

URINE

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (11-dTXb2) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:46**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112530000402    |
| Analyte                   | 11-DTXB2          |
| Sample type               | URINE             |
| Result                    | 249               |
| Result Unit               | PG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 0                 |
| Celerion Study Number     | AA99128-11        |
| Date of Collection        | 2014-MAR-08       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 0                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (11-dTXb2) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:46**

**Generated On: 20 Jul 2016 16:57:04**

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|               |   |
|---------------|---|
| Urine End Day | 1 |
|---------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (iPF2a-III)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:46**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (iPF2a-III) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:46**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112540000402    |
| Analyte                   | IPF2A-III         |
| Sample type               | URINE             |
| Result                    | 89.6              |
| Result Unit               | PG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 0                 |
| Celerion Study Number     | AA99128-12        |
| Date of Collection        | 2014-MAR-08       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 0                 |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (iPF2a-III) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:46**

**Generated On: 20 Jul 2016 16:57:04**

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|               |   |
|---------------|---|
| Urine End Day | 1 |
|---------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Ames)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:48**

**Generated On: 20 Jul 2016 16:57:04**

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Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Ames) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:48**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05113320000127    |
| Analyte                   | AMES              |
| Sample type               | URINE             |
| Result                    | 15.2              |
| Result Unit               | REV/ML            |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | COUNT             |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 0                 |
| Celerion Study Number     | AA99128-15        |
| Date of Collection        | 2014-MAR-08       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 0                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Ames) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:48**

**Generated On: 20 Jul 2016 16:57:04**

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|               |   |
|---------------|---|
| Urine End Day | 1 |
|---------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (1-OHP)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:48**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (1-OHP) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:48**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05115190001565        |
| Analyte                   | 1-OHP                 |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | PG/ML                 |
| Lab Status                | OK                    |
| Sample comment            | NOT ANALYZED IN ERROR |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 0                     |
| Celerion Study Number     | AA99598-03            |
| Date of Collection        | 2014-MAR-08           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 0                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (1-OHP) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:48**

**Generated On: 20 Jul 2016 16:57:04**

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|               |   |
|---------------|---|
| Urine End Day | 1 |
|---------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (SPMA, SBMA)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:46**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

URINE

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (SPMA, SBMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:46**

**Generated On: 20 Jul 2016 16:57:04**

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|                |                |
|----------------|----------------|
| Sample Barcode | 05115170001543 |
|----------------|----------------|

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|         |      |
|---------|------|
| Analyte | SBMA |
|---------|------|

---

|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

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|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | NOT ANALYZED IN ERROR |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

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|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 0 |
|--------------|---|

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|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99598-01 |
|-----------------------|------------|

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|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-08 |
|--------------------|-------------|

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|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

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|                 |   |
|-----------------|---|
| Urine Start Day | 0 |
|-----------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (SPMA, SBMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:46**

**Generated On: 20 Jul 2016 16:57:04**

---

|               |   |
|---------------|---|
| Urine End Day | 1 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (SPMA, SBMA) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:46**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05115170001543        |
| Analyte                   | SPMA                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OK                    |
| Sample comment            | NOT ANALYZED IN ERROR |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 0                     |
| Celerion Study Number     | AA99598-01            |
| Date of Collection        | 2014-MAR-08           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 0                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (SPMA, SBMA) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:46**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (MHBMA)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:46**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (MHBMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:46**

**Generated On: 20 Jul 2016 16:57:04**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05115180001565 |
|----------------|----------------|

---

|         |       |
|---------|-------|
| Analyte | MHBMA |
|---------|-------|

---

|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | NOT ANALYZED IN ERROR |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 0 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99598-02 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-08 |
|--------------------|-------------|

---

|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

---

|                 |   |
|-----------------|---|
| Urine Start Day | 0 |
|-----------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (MHBMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:46**

**Generated On: 20 Jul 2016 16:57:04**

---

|               |   |
|---------------|---|
| Urine End Day | 1 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Creatinine)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:48**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

URINE

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Creatinine) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:48**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05115160001268        |
| Analyte                   | CREATININE            |
| Sample type               | URINE                 |
| Result                    | 74.9                  |
| Result Unit               | MG/DL                 |
| Lab Status                | OK                    |
| 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-MAR-08           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 0                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Urine (Creatinine) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:48**

**Generated On: 20 Jul 2016 16:57:04**

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|               |   |
|---------------|---|
| Urine End Day | 1 |
|---------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Plasma (Nic, Cot, tHCot)**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

PLASMA

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)**

**Generated On: 20 Jul 2016 16:57:04**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05112430001616 |
|----------------|----------------|

---

|         |     |
|---------|-----|
| Analyte | COT |
|---------|-----|

---

|             |        |
|-------------|--------|
| Sample type | PLASMA |
|-------------|--------|

---

|        |     |
|--------|-----|
| Result | 236 |
|--------|-----|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

---

|                |                   |
|----------------|-------------------|
| Sample comment | ANALYZED IN ERROR |
|----------------|-------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 0 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-01 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-08 |
|--------------------|-------------|

---

|                   |   |
|-------------------|---|
| Timepoint-minutes | 0 |
|-------------------|---|

---

|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)**

**Generated On: 20 Jul 2016 16:57:04**

---

|               |   |
|---------------|---|
| Urine End Day | 0 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)**

**Generated On: 20 Jul 2016 16:57:04**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05112430001616 |
|----------------|----------------|

---

|         |     |
|---------|-----|
| Analyte | NIC |
|---------|-----|

---

|             |        |
|-------------|--------|
| Sample type | PLASMA |
|-------------|--------|

---

|        |      |
|--------|------|
| Result | 17.5 |
|--------|------|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

---

|                |                   |
|----------------|-------------------|
| Sample comment | ANALYZED IN ERROR |
|----------------|-------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 0 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-01 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-08 |
|--------------------|-------------|

---

|                   |   |
|-------------------|---|
| Timepoint-minutes | 0 |
|-------------------|---|

---

|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)**

**Generated On: 20 Jul 2016 16:57:04**

---

|               |   |
|---------------|---|
| Urine End Day | 0 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)**

**Generated On: 20 Jul 2016 16:57:04**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05112520000346 |
|----------------|----------------|

---

|         |     |
|---------|-----|
| Analyte | COT |
|---------|-----|

---

|             |        |
|-------------|--------|
| Sample type | PLASMA |
|-------------|--------|

---

|        |     |
|--------|-----|
| Result | 256 |
|--------|-----|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

---

|                |                   |
|----------------|-------------------|
| Sample comment | ANALYZED IN ERROR |
|----------------|-------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 0 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-10 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-08 |
|--------------------|-------------|

---

|                   |   |
|-------------------|---|
| Timepoint-minutes | 0 |
|-------------------|---|

---

|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)**

**Generated On: 20 Jul 2016 16:57:04**

---

|               |   |
|---------------|---|
| Urine End Day | 0 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)**

**Generated On: 20 Jul 2016 16:57:04**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05112520000346 |
|----------------|----------------|

---

|         |       |
|---------|-------|
| Analyte | THCOT |
|---------|-------|

---

|             |        |
|-------------|--------|
| Sample type | PLASMA |
|-------------|--------|

---

|        |      |
|--------|------|
| Result | 58.5 |
|--------|------|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

---

|                |                   |
|----------------|-------------------|
| Sample comment | ANALYZED IN ERROR |
|----------------|-------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 0 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-10 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-08 |
|--------------------|-------------|

---

|                   |   |
|-------------------|---|
| Timepoint-minutes | 0 |
|-------------------|---|

---

|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Baseline (Day 0)**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)**

**Generated On: 20 Jul 2016 16:57:04**

---

|               |   |
|---------------|---|
| Urine End Day | 0 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Date of Visit**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:49**

**Generated On: 20 Jul 2016 16:57:04**

---

Date of Visit

09 MAR 2014  
DD/MMM/YYYY

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Vital Signs**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:49**

**Generated On: 20 Jul 2016 16:57:04**

---

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 09:46  
hour:min 24-hour clock

---

Pulse rate 58  
beats per minute

---

Respiratory rate 18  
breaths per minute

---

Blood Pressure (systolic) 130  
mmHg

---

Blood Pressure (diastolic) 80  
mmHg

---

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Plasma Nicotine Sample**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:49**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

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

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 09 MAR 2014 |
|---------------------|-------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 20:21 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Plasma Cotinine Sample**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:49**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

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

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 09 MAR 2014 |
|---------------------|-------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 20:21 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: CoHb Blood Sample**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:49**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

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

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 09 MAR 2014 |
|---------------------|-------------|

---

|           |  |
|-----------|--|
| Timepoint | 20:00 - 21:30 <input checked="" type="radio"/> |
|-----------|--|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 20:21 |
|--------------------------------|-------|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: CO Breath Test (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:49**

**Generated On: 20 Jul 2016 16:57:04**

---

|                     |       |
|---------------------|-------|
| 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 | 06:52 |
|---|-------|

---

|             |    |
|-------------|----|
| Result(ppm) | 10 |
|-------------|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: CO Breath Test (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:49**

**Generated On: 20 Jul 2016 16:57:04**

---

|                     |       |
|---------------------|-------|
| 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 | 12:47 |
|---|-------|

---

|             |   |
|-------------|---|
| Result(ppm) | 6 |
|-------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: CO Breath Test (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:49**

**Generated On: 20 Jul 2016 16:57:04**

---

|                     |       |
|---------------------|-------|
| 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 | 16:15 |
|---|-------|

---

|             |   |
|-------------|---|
| Result(ppm) | 3 |
|-------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: CO Breath Test (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:49**

**Generated On: 20 Jul 2016 16:57:04**

---

|                     |       |
|---------------------|-------|
| 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 | 20:05 |
|---|-------|

---

|             |   |
|-------------|---|
| Result(ppm) | 2 |
|-------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: 24 hour urine collections**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:49**

**Generated On: 20 Jul 2016 16:57:04**

---

|            |                        |
|------------|------------------------|
| Start Time | 06:13                  |
|            | hour:min 24-hour clock |

---

|          |             |
|----------|-------------|
| End Date | 10 MAR 2014 |
|          | DD/MMM/YYYY |

---

|          |                        |
|----------|------------------------|
| End Time | 06:07                  |
|          | hour:min 24-hour clock |

---

|        |      |
|--------|------|
| Volume | 1863 |
|        | mL   |

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Sample Urine Collection**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:49**

**Generated On: 20 Jul 2016 16:57:04**

---

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?

11

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:49**

**Generated On: 20 Jul 2016 16:57:04**

---

Date of Birth

(b) (6)

---

Date of assessment  
DD/MMM/YYYY

2014 MAR 09  
DD/MMM/YYYY

---

Time of assessment

06:27  
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?

Mild ☐

4. Desire or craving to smoke

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:49**

**Generated On: 20 Jul 2016 16:57:04**

---

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? None ☐

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: 1194**

**Folder: Day 1**

**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:49**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Day 1**

**Form: Cough Assessment**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:49**

**Generated On: 20 Jul 2016 16:57:04**

---

Date of Birth

(b) (6)

---

Date of assessment  
DD/MMM/YYYY

2014 MAR 09  
DD/MMM/YYYY

---

Time of assessment

06:26  
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: 1194**

**Folder: Day 1**

**Form: Lab\_BU\_COHB (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:49**

**Generated On: 20 Jul 2016 16:57:04**

|                               |                    |
|-------------------------------|--------------------|
| Sample Barcode                | 05115150001268     |
| Analyte                       | CARBOXYHEMOGLOBIN  |
| Sample type                   | BLOOD              |
| Result                        | 2.40               |
| Result Unit                   | %                  |
| Lab Status                    | OK                 |
| Sample comment                | .                  |
| 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-MAR-09        |
| Timepoint-minutes             |                    |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Lab\_BU\_COHB (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:49**

**Generated On: 20 Jul 2016 16:57:04**

---

Start Day (24 hour urine only)

---

End Day (24 hour Urine Only)

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:49**

**Generated On: 20 Jul 2016 16:57:04**

---

Date of Birth

(b) (6)

---

Date of assessment

2014 MAR 09

DD/MMM/YYYY

DD/MMM/YYYY

---

Time of assessment

20:02

hour:min 24-hour clock

---

Assessment Status

Completed ☐

---

1. Was smoking satisfying?

Very little ☐

---

2. Did cigarettes taste good?

Very little ☐

---

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?

Very little ☐

---

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?

Very little ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:49**

**Generated On: 20 Jul 2016 16:57:04**

---

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? Quite a lot ☐

---

12. Did you enjoy smoking? Moderately ☐

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Questionnaire on smoking urges (QSU)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:49**

**Generated On: 20 Jul 2016 16:57:04**

|  |                                 |
|--|---------------------------------|
| Type   | QSU                             |
| Date of Birth  | (b) (6)                         |
| Date of assessment<br>DD/MMM/YYYY                                | 2014 MAR 09                     |
| Time of assessment<br>hour:min 24-hour clock                     | 20:01                           |
| Assessment Status  | Completed <input type="radio"/> |
| 1. I have a desire for a cigarette right now                     | Disagree <input type="radio"/>  |
| 2. Nothing would be better than smoking a cigarette<br>right now | Disagree <input type="radio"/>  |
| 3. If it were possible I would probably smoke now                | 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                           | Disagree <input type="radio"/>  |
| 6. I have an urge for a cigarette                                | Disagree <input type="radio"/>  |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Questionnaire on smoking urges (QSU)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:49**

**Generated On: 20 Jul 2016 16:57:04**

---

7. A cigarette would taste good now Disagree ☐

---

8. I would do almost anything for a cigarette now Disagree ☐

---

9. Smoking would make me less depressed Strongly disagree ☐

---

10. I am going to smoke as soon as possible Disagree ☐

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:50**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:50**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112450002134    |
| Analyte                   | HPMA              |
| Sample type               | URINE             |
| Result                    | 369               |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 1                 |
| Celerion Study Number     | AA99128-03        |
| Date of Collection        | 2014-MAR-09       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 1                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:50**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

---

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:50**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112450002134    |
| Analyte                   | CEMA              |
| Sample type               | URINE             |
| Result                    | 25.0              |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 1                 |
| Celerion Study Number     | AA99128-03        |
| Date of Collection        | 2014-MAR-09       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 1                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:50**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

---

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:50**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112450002134    |
| Analyte                   | HBMA              |
| Sample type               | URINE             |
| Result                    | 296               |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 1                 |
| Celerion Study Number     | AA99128-03        |
| Date of Collection        | 2014-MAR-09       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 1                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:50**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

---

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (NNN, NNAL)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:49**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

URINE

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (NNN, NNAL) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:49**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112460002545    |
| Analyte                   | NNAL              |
| Sample type               | URINE             |
| Result                    | 40.3              |
| Result Unit               | PG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 1                 |
| Celerion Study Number     | AA99128-04        |
| Date of Collection        | 2014-MAR-09       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 1                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (NNN, NNAL) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:49**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

---

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (NNN, NNAL) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:49**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112460002545    |
| Analyte                   | NNN               |
| Sample type               | URINE             |
| Result                    | 0.533             |
| Result Unit               | PG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 1                 |
| Celerion Study Number     | AA99128-04        |
| Date of Collection        | 2014-MAR-09       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 1                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (NNN, NNAL) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:49**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

2

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (HEMA)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:50**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (HEMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:50**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112470001269    |
| Analyte                   | HEMA              |
| Sample type               | URINE             |
| Result                    | 2.56              |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 1                 |
| Celerion Study Number     | AA99128-05        |
| Date of Collection        | 2014-MAR-09       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 1                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (HEMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:50**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

---

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:50**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

URINE

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:50**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112480000664    |
| Analyte                   | COT               |
| Sample type               | URINE             |
| Result                    | 1200              |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 1                 |
| Celerion Study Number     | AA99128-06        |
| Date of Collection        | 2014-MAR-10       |
| Timepoint-minutes         |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:50**

**Generated On: 20 Jul 2016 16:57:04**

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|                 |   |
|-----------------|---|
| Urine Start Day | 1 |
|-----------------|---|

---

|               |   |
|---------------|---|
| Urine End Day | 2 |
|---------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:50**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112480000664    |
| Analyte                   | COT-GLUC          |
| Sample type               | URINE             |
| Result                    | 1720              |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 1                 |
| Celerion Study Number     | AA99128-06        |
| Date of Collection        | 2014-MAR-10       |
| Timepoint-minutes         |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:50**

**Generated On: 20 Jul 2016 16:57:04**

---

|                 |   |
|-----------------|---|
| Urine Start Day | 1 |
|-----------------|---|

---

|               |   |
|---------------|---|
| Urine End Day | 2 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:50**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112480000664    |
| Analyte                   | NIC               |
| Sample type               | URINE             |
| Result                    | 314               |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 1                 |
| Celerion Study Number     | AA99128-06        |
| Date of Collection        | 2014-MAR-10       |
| Timepoint-minutes         |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:50**

**Generated On: 20 Jul 2016 16:57:04**

---

|                 |   |
|-----------------|---|
| Urine Start Day | 1 |
|-----------------|---|

---

|               |   |
|---------------|---|
| Urine End Day | 2 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:50**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112480000664    |
| Analyte                   | NIC-GLUC          |
| Sample type               | URINE             |
| Result                    | 345               |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 1                 |
| Celerion Study Number     | AA99128-06        |
| Date of Collection        | 2014-MAR-10       |
| Timepoint-minutes         |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:50**

**Generated On: 20 Jul 2016 16:57:04**

---

|                 |   |
|-----------------|---|
| Urine Start Day | 1 |
|-----------------|---|

---

|               |   |
|---------------|---|
| Urine End Day | 2 |
|---------------|---|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(5)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:50**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112480000664    |
| Analyte                   | THCOT             |
| Sample type               | URINE             |
| Result                    | 1930              |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 1                 |
| Celerion Study Number     | AA99128-06        |
| Date of Collection        | 2014-MAR-10       |
| Timepoint-minutes         |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(5)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:50**

**Generated On: 20 Jul 2016 16:57:04**

---

|                 |   |
|-----------------|---|
| Urine Start Day | 1 |
|-----------------|---|

---

|               |   |
|---------------|---|
| Urine End Day | 2 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(6)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:50**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112480000664    |
| Analyte                   | THCOT-GLUC        |
| Sample type               | URINE             |
| Result                    | 730               |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 1                 |
| Celerion Study Number     | AA99128-06        |
| Date of Collection        | 2014-MAR-10       |
| Timepoint-minutes         |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(6)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:50**

**Generated On: 20 Jul 2016 16:57:04**

---

|                 |   |
|-----------------|---|
| Urine Start Day | 1 |
|-----------------|---|

---

|               |   |
|---------------|---|
| Urine End Day | 2 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (3-OH BaP)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:51**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (3-OH BaP) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:51**

**Generated On: 20 Jul 2016 16:57:04**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05112490001269 |
|----------------|----------------|

---

|         |          |
|---------|----------|
| Analyte | 3-OH BAP |
|---------|----------|

---

|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

---

|        |      |
|--------|------|
| Result | 41.1 |
|--------|------|

---

|             |       |
|-------------|-------|
| Result Unit | FG/ML |
|-------------|-------|

---

|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

---

|                |                   |
|----------------|-------------------|
| Sample comment | ANALYZED IN ERROR |
|----------------|-------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 1 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-07 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-09 |
|--------------------|-------------|

---

|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

---

|                 |   |
|-----------------|---|
| Urine Start Day | 1 |
|-----------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (3-OH BaP) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:51**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

---

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:51**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

URINE

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:51**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112510001291    |
| Analyte                   | 1-NA              |
| Sample type               | URINE             |
| Result                    | 9.12              |
| Result Unit               | PG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 1                 |
| Celerion Study Number     | AA99128-09        |
| Date of Collection        | 2014-MAR-09       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 1                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:51**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

---

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:51**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112510001291    |
| Analyte                   | 2-NA              |
| Sample type               | URINE             |
| Result                    | 3.67              |
| Result Unit               | PG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 1                 |
| Celerion Study Number     | AA99128-09        |
| Date of Collection        | 2014-MAR-09       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 1                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:51**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

---

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:51**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112510001291    |
| Analyte                   | 4-ABP             |
| Sample type               | URINE             |
| Result                    | 2.58              |
| Result Unit               | PG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 1                 |
| Celerion Study Number     | AA99128-09        |
| Date of Collection        | 2014-MAR-09       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 1                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:51**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

---

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:51**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112510001291    |
| Analyte                   | O-TOL             |
| Sample type               | URINE             |
| Result                    | BLQ<(50.0)        |
| Result Unit               | PG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 1                 |
| Celerion Study Number     | AA99128-09        |
| Date of Collection        | 2014-MAR-09       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 1                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:51**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

---

2



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (1-OHP)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:51**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (1-OHP) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:51**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05115190001566        |
| Analyte                   | 1-OHP                 |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | PG/ML                 |
| Lab Status                | OK                    |
| Sample comment            | NOT ANALYZED IN ERROR |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 1                     |
| Celerion Study Number     | AA99598-03            |
| Date of Collection        | 2014-MAR-09           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 1                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (1-OHP) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:51**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

---

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (SPMA, SBMA)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:50**

**Generated On: 20 Jul 2016 16:57:04**

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Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (SPMA, SBMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:50**

**Generated On: 20 Jul 2016 16:57:04**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05115170001544 |
|----------------|----------------|

---

|         |      |
|---------|------|
| Analyte | SBMA |
|---------|------|

---

|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | NOT ANALYZED IN ERROR |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 1 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99598-01 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-09 |
|--------------------|-------------|

---

|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

---

|                 |   |
|-----------------|---|
| Urine Start Day | 1 |
|-----------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (SPMA, SBMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:50**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

---

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (SPMA, SBMA) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:50**

**Generated On: 20 Jul 2016 16:57:04**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05115170001544 |
|----------------|----------------|

---

|         |      |
|---------|------|
| Analyte | SPMA |
|---------|------|

---

|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | NOT ANALYZED IN ERROR |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 1 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99598-01 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-09 |
|--------------------|-------------|

---

|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

---

|                 |   |
|-----------------|---|
| Urine Start Day | 1 |
|-----------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (SPMA, SBMA) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:50**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

---

2



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (MHBMA)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:50**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (MHBMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:50**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05115180001566        |
| Analyte                   | MHBMA                 |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OK                    |
| Sample comment            | NOT ANALYZED IN ERROR |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 1                     |
| Celerion Study Number     | AA99598-02            |
| Date of Collection        | 2014-MAR-09           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 1                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (MHBMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:50**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

---

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (Creatinine)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:51**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (Creatinine) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:51**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05115160001269        |
| Analyte                   | CREATININE            |
| Sample type               | URINE                 |
| Result                    | 123                   |
| Result Unit               | MG/DL                 |
| Lab Status                | OK                    |
| 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-MAR-09           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 1                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Urine (Creatinine) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:51**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

---

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Plasma (Nic, Cot, tHCot)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:50**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

PLASMA

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:50**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112430001617    |
| Analyte                   | COT               |
| Sample type               | PLASMA            |
| Result                    | 200               |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 1                 |
| Celerion Study Number     | AA99128-01        |
| Date of Collection        | 2014-MAR-09       |
| Timepoint-minutes         | 0                 |
| Urine Start Day           |                   |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:50**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:50**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112430001617    |
| Analyte                   | NIC               |
| Sample type               | PLASMA            |
| Result                    | 9.76              |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 1                 |
| Celerion Study Number     | AA99128-01        |
| Date of Collection        | 2014-MAR-09       |
| Timepoint-minutes         | 0                 |
| Urine Start Day           |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 1**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:50**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Date of Visit**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:51**

**Generated On: 20 Jul 2016 16:57:04**

---

Date of Visit

10 MAR 2014  
DD/MMM/YYYY

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Vital Signs**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:51**

**Generated On: 20 Jul 2016 16:57:04**

---

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

09:12  
hour:min 24-hour clock

---

Pulse rate

58  
beats per minute

---

Respiratory rate

20  
breaths per minute

---

Blood Pressure (systolic)

134  
mmHg

---

Blood Pressure (diastolic)

80  
mmHg

---

Vital Signs Position of Subject

Supine ☒

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Plasma Nicotine Sample**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:51**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

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

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 10 MAR 2014 |
|---------------------|-------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 20:08 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Plasma Cotinine Sample**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:51**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

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

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 10 MAR 2014 |
|---------------------|-------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 20:08 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: CoHb Blood Sample**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:51**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

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

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 10 MAR 2014 |
|---------------------|-------------|

---

|           |  |
|-----------|--|
| Timepoint | 20:00 - 21:30 <input checked="" type="radio"/> |
|-----------|--|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 20:08 |
|--------------------------------|-------|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: CO Breath Test (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:51**

**Generated On: 20 Jul 2016 16:57:04**

---

|                     |       |
|---------------------|-------|
| 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 | 06:30 |
|---|-------|

---

|             |   |
|-------------|---|
| Result(ppm) | 3 |
|-------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: CO Breath Test (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:51**

**Generated On: 20 Jul 2016 16:57:04**

---

|                     |       |
|---------------------|-------|
| 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 | 12:23 |
|---|-------|

---

|             |   |
|-------------|---|
| Result(ppm) | 2 |
|-------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: CO Breath Test (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:51**

**Generated On: 20 Jul 2016 16:57:04**

---

|                     |       |
|---------------------|-------|
| 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 | 16:04 |
|---|-------|

---

|             |   |
|-------------|---|
| Result(ppm) | 2 |
|-------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: CO Breath Test (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:51**

**Generated On: 20 Jul 2016 16:57:04**

---

|                     |       |
|---------------------|-------|
| 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 | 20:04 |
|---|-------|

---

|             |   |
|-------------|---|
| Result(ppm) | 2 |
|-------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: 24 hour urine collections**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:51**

**Generated On: 20 Jul 2016 16:57:04**

---

|            |                        |
|------------|------------------------|
| Start Time | 06:07                  |
|            | hour:min 24-hour clock |

---

|          |             |
|----------|-------------|
| End Date | 11 MAR 2014 |
|          | DD/MMM/YYYY |

---

|          |                        |
|----------|------------------------|
| End Time | 06:01                  |
|          | hour:min 24-hour clock |

---

|        |      |
|--------|------|
| Volume | 1920 |
|        | mL   |

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Sample Urine Collection**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:51**

**Generated On: 20 Jul 2016 16:57:04**

---

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? 11

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:52**

**Generated On: 20 Jul 2016 16:57:04**

---

Date of Birth

(b) (6)

---

Date of assessment  
DD/MMM/YYYY

2014 MAR 10  
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?

Mild ☐

4. Desire or craving to smoke

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:52**

**Generated On: 20 Jul 2016 16:57:04**

---

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? 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? None ☐

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: 1194**

**Folder: Day 2**

**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:52**

**Generated On: 20 Jul 2016 16:57:04**

---

How have you been feeling over the past 24 hours?

Slight ☒

13. Dreaming or nightmares

---

How have you been feeling over the past 24 hours?

Slight ☒

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: 1194**

**Folder: Day 2**

**Form: Cough Assessment**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:52**

**Generated On: 20 Jul 2016 16:57:04**

---

Date of Birth

(b) (6)

---

Date of assessment  
DD/MMM/YYYY

2014 MAR 10  
DD/MMM/YYYY

---

Time of assessment

06:01  
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: 1194**

**Folder: Day 2**

**Form: Lab\_BU\_COHB (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:52**

**Generated On: 20 Jul 2016 16:57:04**

|                               |                    |
|-------------------------------|--------------------|
| Sample Barcode                | 05115150001269     |
| Analyte                       | CARBOXYHEMOGLOBIN  |
| Sample type                   | BLOOD              |
| Result                        | 2.40               |
| Result Unit                   | %                  |
| Lab Status                    | OK                 |
| Sample comment                | .                  |
| 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-MAR-10        |
| Timepoint-minutes             |                    |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Lab\_BU\_COHB (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:52**

**Generated On: 20 Jul 2016 16:57:04**

---

Start Day (24 hour urine only)

---

End Day (24 hour Urine Only)

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:52**

**Generated On: 20 Jul 2016 16:57:04**

---

Date of Birth

(b) (6)

---

Date of assessment

2014 MAR 10

DD/MMM/YYYY

DD/MMM/YYYY

---

Time of assessment

20:02

hour:min 24-hour clock

---

Assessment Status

Completed

---

1. Was smoking satisfying?

Moderately

---

2. Did cigarettes taste good?

Not at all

---

3. Did you enjoy the sensation in your throat and chest?

Moderately

---

4. Did smoking calm you down?

Moderately

---

5. Did smoking make you feel more awake?

Not at all

---

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?

Not at all

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:52**

**Generated On: 20 Jul 2016 16:57:04**

---

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? Quite a lot ☐

---

12. Did you enjoy smoking? Moderately ☐

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Questionnaire on smoking urges (QSU)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:52**

**Generated On: 20 Jul 2016 16:57:04**

---

|      |     |
|------|-----|
| Type | QSU |
|------|-----|

---

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

---

|                    |             |
|--------------------|-------------|
| Date of assessment | 2014 MAR 10 |
|--------------------|-------------|

DD/MMM/YYYY

---

|                    |       |
|--------------------|-------|
| Time of assessment | 20:01 |
|--------------------|-------|

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 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 | Strongly 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 | Somewhat agree <input checked="" type="radio"/> |
|-----------------------------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Questionnaire on smoking urges (QSU)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:52**

**Generated On: 20 Jul 2016 16:57:04**

---

7. A cigarette would taste good now Do not agree or disagree ☐

---

8. I would do almost anything for a cigarette now Strongly 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: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:52**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:52**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112450002135    |
| Analyte                   | HPMA              |
| Sample type               | URINE             |
| Result                    | 377               |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 2                 |
| Celerion Study Number     | AA99128-03        |
| Date of Collection        | 2014-MAR-10       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 2                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:52**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

3

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:52**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112450002135    |
| Analyte                   | CEMA              |
| Sample type               | URINE             |
| Result                    | 16.6              |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 2                 |
| Celerion Study Number     | AA99128-03        |
| Date of Collection        | 2014-MAR-10       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 2                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:52**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

3

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:52**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112450002135    |
| Analyte                   | HBMA              |
| Sample type               | URINE             |
| Result                    | 239               |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 2                 |
| Celerion Study Number     | AA99128-03        |
| Date of Collection        | 2014-MAR-10       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 2                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (CEMA, HPMa, HBMA) (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:52**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

3

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (NNN, NNAL)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:52**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

URINE

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (NNN, NNAL) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:52**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112460002546    |
| Analyte                   | NNAL              |
| Sample type               | URINE             |
| Result                    | 26.8              |
| Result Unit               | PG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 2                 |
| Celerion Study Number     | AA99128-04        |
| Date of Collection        | 2014-MAR-10       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 2                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (NNN, NNAL) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:52**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

3

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (NNN, NNAL) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:52**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112460002546    |
| Analyte                   | NNN               |
| Sample type               | URINE             |
| Result                    | 0.288             |
| Result Unit               | PG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 2                 |
| Celerion Study Number     | AA99128-04        |
| Date of Collection        | 2014-MAR-10       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 2                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (NNN, NNAL) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:52**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

3

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (HEMA)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:52**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (HEMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:52**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112470001270    |
| Analyte                   | HEMA              |
| Sample type               | URINE             |
| Result                    | 1.35              |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 2                 |
| Celerion Study Number     | AA99128-05        |
| Date of Collection        | 2014-MAR-10       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 2                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (HEMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:52**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

---

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:52**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

URINE

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:52**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112480000665    |
| Analyte                   | COT               |
| Sample type               | URINE             |
| Result                    | 1020              |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 2                 |
| Celerion Study Number     | AA99128-06        |
| Date of Collection        | 2014-MAR-11       |
| Timepoint-minutes         |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:52**

**Generated On: 20 Jul 2016 16:57:04**

---

|                 |   |
|-----------------|---|
| Urine Start Day | 2 |
|-----------------|---|

---

|               |   |
|---------------|---|
| Urine End Day | 3 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:52**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112480000665    |
| Analyte                   | COT-GLUC          |
| Sample type               | URINE             |
| Result                    | 1250              |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 2                 |
| Celerion Study Number     | AA99128-06        |
| Date of Collection        | 2014-MAR-11       |
| Timepoint-minutes         |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:52**

**Generated On: 20 Jul 2016 16:57:04**

---

|                 |   |
|-----------------|---|
| Urine Start Day | 2 |
|-----------------|---|

---

|               |   |
|---------------|---|
| Urine End Day | 3 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:52**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112480000665    |
| Analyte                   | NIC               |
| Sample type               | URINE             |
| Result                    | 286               |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 2                 |
| Celerion Study Number     | AA99128-06        |
| Date of Collection        | 2014-MAR-11       |
| Timepoint-minutes         |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:52**

**Generated On: 20 Jul 2016 16:57:04**

---

|                 |   |
|-----------------|---|
| Urine Start Day | 2 |
|-----------------|---|

---

|               |   |
|---------------|---|
| Urine End Day | 3 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:52**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112480000665    |
| Analyte                   | NIC-GLUC          |
| Sample type               | URINE             |
| Result                    | 249               |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 2                 |
| Celerion Study Number     | AA99128-06        |
| Date of Collection        | 2014-MAR-11       |
| Timepoint-minutes         |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:52**

**Generated On: 20 Jul 2016 16:57:04**

---

|                 |   |
|-----------------|---|
| Urine Start Day | 2 |
|-----------------|---|

---

|               |   |
|---------------|---|
| Urine End Day | 3 |
|---------------|---|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(5)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:52**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112480000665    |
| Analyte                   | THCOT             |
| Sample type               | URINE             |
| Result                    | 1800              |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 2                 |
| Celerion Study Number     | AA99128-06        |
| Date of Collection        | 2014-MAR-11       |
| Timepoint-minutes         |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(5)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:52**

**Generated On: 20 Jul 2016 16:57:04**

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|                 |   |
|-----------------|---|
| Urine Start Day | 2 |
|-----------------|---|

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|               |   |
|---------------|---|
| Urine End Day | 3 |
|---------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(6)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:52**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112480000665    |
| Analyte                   | THCOT-GLUC        |
| Sample type               | URINE             |
| Result                    | 679               |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 2                 |
| Celerion Study Number     | AA99128-06        |
| Date of Collection        | 2014-MAR-11       |
| Timepoint-minutes         |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(6)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:52**

**Generated On: 20 Jul 2016 16:57:04**

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|                 |   |
|-----------------|---|
| Urine Start Day | 2 |
|-----------------|---|

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|               |   |
|---------------|---|
| Urine End Day | 3 |
|---------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (3-OH BaP)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:53**

**Generated On: 20 Jul 2016 16:57:04**

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Sample type

URINE

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (3-OH BaP) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:53**

**Generated On: 20 Jul 2016 16:57:04**

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|                |                |
|----------------|----------------|
| Sample Barcode | 05112490001270 |
|----------------|----------------|

---

|         |          |
|---------|----------|
| Analyte | 3-OH BAP |
|---------|----------|

---

|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

---

|        |            |
|--------|------------|
| Result | BLQ<(25.0) |
|--------|------------|

---

|             |       |
|-------------|-------|
| Result Unit | FG/ML |
|-------------|-------|

---

|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

---

|                |                   |
|----------------|-------------------|
| Sample comment | ANALYZED IN ERROR |
|----------------|-------------------|

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|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 2 |
|--------------|---|

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|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-07 |
|-----------------------|------------|

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|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-10 |
|--------------------|-------------|

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|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

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|                 |   |
|-----------------|---|
| Urine Start Day | 2 |
|-----------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (3-OH BaP) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:53**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

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3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:53**

**Generated On: 20 Jul 2016 16:57:04**

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Sample type

URINE

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:53**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112510001292    |
| Analyte                   | 1-NA              |
| Sample type               | URINE             |
| Result                    | 4.09              |
| Result Unit               | PG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 2                 |
| Celerion Study Number     | AA99128-09        |
| Date of Collection        | 2014-MAR-10       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 2                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:53**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

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3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:53**

**Generated On: 20 Jul 2016 16:57:04**

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|                |                |
|----------------|----------------|
| Sample Barcode | 05112510001292 |
|----------------|----------------|

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|         |      |
|---------|------|
| Analyte | 2-NA |
|---------|------|

---

|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

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|        |            |
|--------|------------|
| Result | BLQ<(2.50) |
|--------|------------|

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|             |       |
|-------------|-------|
| Result Unit | PG/ML |
|-------------|-------|

---

|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

---

|                |                   |
|----------------|-------------------|
| Sample comment | ANALYZED IN ERROR |
|----------------|-------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

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|              |   |
|--------------|---|
| Day of Visit | 2 |
|--------------|---|

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|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-09 |
|-----------------------|------------|

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|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-10 |
|--------------------|-------------|

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|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

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|                 |   |
|-----------------|---|
| Urine Start Day | 2 |
|-----------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:53**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

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3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:53**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112510001292    |
| Analyte                   | 4-ABP             |
| Sample type               | URINE             |
| Result                    | BLQ<(1.50)        |
| Result Unit               | PG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 2                 |
| Celerion Study Number     | AA99128-09        |
| Date of Collection        | 2014-MAR-10       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 2                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:53**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

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3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:53**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112510001292    |
| Analyte                   | O-TOL             |
| Sample type               | URINE             |
| Result                    | BLQ<(50.0)        |
| Result Unit               | PG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 2                 |
| Celerion Study Number     | AA99128-09        |
| Date of Collection        | 2014-MAR-10       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 2                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:53**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

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3



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (1-OHP)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:53**

**Generated On: 20 Jul 2016 16:57:04**

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Sample type

URINE

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (1-OHP) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:53**

**Generated On: 20 Jul 2016 16:57:04**

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|                |                |
|----------------|----------------|
| Sample Barcode | 05115190001567 |
|----------------|----------------|

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|         |       |
|---------|-------|
| Analyte | 1-OHP |
|---------|-------|

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|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

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|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | PG/ML |
|-------------|-------|

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|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | NOT ANALYZED IN ERROR |
|----------------|-----------------------|

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|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 2 |
|--------------|---|

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|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99598-03 |
|-----------------------|------------|

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|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-10 |
|--------------------|-------------|

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|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

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|                 |   |
|-----------------|---|
| Urine Start Day | 2 |
|-----------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (1-OHP) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:53**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

3

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (SPMA, SBMA)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:52**

**Generated On: 20 Jul 2016 16:57:04**

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Sample type

URINE

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (SPMA, SBMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:52**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05115170001545        |
| Analyte                   | SBMA                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OK                    |
| Sample comment            | NOT ANALYZED IN ERROR |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 2                     |
| Celerion Study Number     | AA99598-01            |
| Date of Collection        | 2014-MAR-10           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 2                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (SPMA, SBMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:52**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

3

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (SPMA, SBMA) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:52**

**Generated On: 20 Jul 2016 16:57:04**

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|                |                |
|----------------|----------------|
| Sample Barcode | 05115170001545 |
|----------------|----------------|

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|         |      |
|---------|------|
| Analyte | SPMA |
|---------|------|

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|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

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|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | NOT ANALYZED IN ERROR |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 2 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99598-01 |
|-----------------------|------------|

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|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-10 |
|--------------------|-------------|

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|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

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|                 |   |
|-----------------|---|
| Urine Start Day | 2 |
|-----------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (SPMA, SBMA) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:52**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

3

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (MHBMA)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:52**

**Generated On: 20 Jul 2016 16:57:04**

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Sample type

URINE

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (MHBMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:52**

**Generated On: 20 Jul 2016 16:57:04**

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|                |                |
|----------------|----------------|
| Sample Barcode | 05115180001567 |
|----------------|----------------|

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|         |       |
|---------|-------|
| Analyte | MHBMA |
|---------|-------|

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|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

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|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | NOT ANALYZED IN ERROR |
|----------------|-----------------------|

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|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

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|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

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|              |   |
|--------------|---|
| Day of Visit | 2 |
|--------------|---|

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|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99598-02 |
|-----------------------|------------|

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|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-10 |
|--------------------|-------------|

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|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

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|                 |   |
|-----------------|---|
| Urine Start Day | 2 |
|-----------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (MHBMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:52**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

3

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (Creatinine)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:53**

**Generated On: 20 Jul 2016 16:57:04**

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Sample type

URINE

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (Creatinine) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:53**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05115160001270        |
| Analyte                   | CREATININE            |
| Sample type               | URINE                 |
| Result                    | 114                   |
| Result Unit               | MG/DL                 |
| Lab Status                | OK                    |
| 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-MAR-10           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 2                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Urine (Creatinine) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:53**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

3

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Plasma (Nic, Cot, tHCot)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:52**

**Generated On: 20 Jul 2016 16:57:04**

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Sample type

PLASMA

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:52**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112430001618    |
| Analyte                   | COT               |
| Sample type               | PLASMA            |
| Result                    | 216               |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 2                 |
| Celerion Study Number     | AA99128-01        |
| Date of Collection        | 2014-MAR-10       |
| Timepoint-minutes         | 0                 |
| Urine Start Day           |                   |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:52**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

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2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:52**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112430001618    |
| Analyte                   | NIC               |
| Sample type               | PLASMA            |
| Result                    | 11.6              |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 2                 |
| Celerion Study Number     | AA99128-01        |
| Date of Collection        | 2014-MAR-10       |
| Timepoint-minutes         | 0                 |
| Urine Start Day           |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 2**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:52**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

2

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Date of Visit**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:53**

**Generated On: 20 Jul 2016 16:57:04**

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Date of Visit

11 MAR 2014  
DD/MMM/YYYY

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Vital Signs**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:53**

**Generated On: 20 Jul 2016 16:57:04**

---

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

09:27  
hour:min 24-hour clock

---

Pulse rate

61  
beats per minute

---

Respiratory rate

14  
breaths per minute

---

Blood Pressure (systolic)

120  
mmHg

---

Blood Pressure (diastolic)

76  
mmHg

---

Vital Signs Position of Subject

Supine ☒

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Plasma Nicotine Sample**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:53**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

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

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 11 MAR 2014 |
|---------------------|-------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 20:22 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Plasma Cotinine Sample**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:53**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

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

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 11 MAR 2014 |
|---------------------|-------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 20:22 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: CoHb Blood Sample**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:53**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

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

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 11 MAR 2014 |
|---------------------|-------------|

---

|           |  |
|-----------|--|
| Timepoint | 20:00 - 21:30 <input checked="" type="radio"/> |
|-----------|--|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 20:22 |
|--------------------------------|-------|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: CO Breath Test (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:53**

**Generated On: 20 Jul 2016 16:57:04**

---

|                     |       |
|---------------------|-------|
| 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 | 06:29 |
|---|-------|

---

|             |   |
|-------------|---|
| Result(ppm) | 1 |
|-------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: CO Breath Test (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:53**

**Generated On: 20 Jul 2016 16:57:04**

---

|                     |       |
|---------------------|-------|
| 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 | 12:23 |
|---|-------|

---

|             |   |
|-------------|---|
| Result(ppm) | 3 |
|-------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: CO Breath Test (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:53**

**Generated On: 20 Jul 2016 16:57:04**

---

|                     |       |
|---------------------|-------|
| 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 | 16:05 |
|---|-------|

---

|             |   |
|-------------|---|
| Result(ppm) | 3 |
|-------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: CO Breath Test (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:53**

**Generated On: 20 Jul 2016 16:57:04**

---

|                     |       |
|---------------------|-------|
| 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 | 20:06 |
|---|-------|

---

|             |   |
|-------------|---|
| Result(ppm) | 1 |
|-------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: 24 hour urine collections**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:53**

**Generated On: 20 Jul 2016 16:57:04**

---

|            |                        |
|------------|------------------------|
| Start Time | 06:01                  |
|            | hour:min 24-hour clock |

---

|          |             |
|----------|-------------|
| End Date | 12 MAR 2014 |
|          | DD/MMM/YYYY |

---

|          |                        |
|----------|------------------------|
| End Time | 06:02                  |
|          | hour:min 24-hour clock |

---

|        |      |
|--------|------|
| Volume | 2140 |
|        | mL   |

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Sample Urine Collection**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:53**

**Generated On: 20 Jul 2016 16:57:04**

---

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?

11

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:54**

**Generated On: 20 Jul 2016 16:57:04**

---

Date of Birth

(b) (6)

---

Date of assessment  
DD/MMM/YYYY

2014 MAR 11  
DD/MMM/YYYY

---

Time of assessment

05:54  
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?

Mild ☐

4. Desire or craving to smoke

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:54**

**Generated On: 20 Jul 2016 16:57:04**

---

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? 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? None ☐

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: 1194**

**Folder: Day 3**

**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:54**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Day 3**

**Form: Cough Assessment**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:53**

**Generated On: 20 Jul 2016 16:57:04**

---

Date of Birth

(b) (6)

---

Date of assessment  
DD/MMM/YYYY

2014 MAR 11  
DD/MMM/YYYY

---

Time of assessment

05:53  
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: 1194**

**Folder: Day 3**

**Form: Lab\_BU\_COHB (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:54**

**Generated On: 20 Jul 2016 16:57:04**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05115150001270 |
|----------------|----------------|

---

|         |                   |
|---------|-------------------|
| Analyte | CARBOXYHEMOGLOBIN |
|---------|-------------------|

---

|             |       |
|-------------|-------|
| Sample type | BLOOD |
|-------------|-------|

---

|        |      |
|--------|------|
| Result | 2.10 |
|--------|------|

---

|             |   |
|-------------|---|
| Result Unit | % |
|-------------|---|

---

|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

---

|                |   |
|----------------|---|
| Sample comment | . |
|----------------|---|

---

|                  |                    |
|------------------|--------------------|
| 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-MAR-11 |
|--------------------|-------------|

---

|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

---

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Lab\_BU\_COHB (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:54**

**Generated On: 20 Jul 2016 16:57:04**

---

Start Day (24 hour urine only) \_\_\_\_\_

---

End Day (24 hour Urine Only) \_\_\_\_\_

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:54**

**Generated On: 20 Jul 2016 16:57:04**

---

Date of Birth

(b) (6)

---

Date of assessment

2014 MAR 11

DD/MMM/YYYY

DD/MMM/YYYY

---

Time of assessment

20:02

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?

Not at all ☒

---

6. Did smoking make you feel less irritable?

Not at all ☒

---

7. Did smoking help you concentrate?

Moderately ☒

---

8. Did smoking reduce your hunger for food?

Not at all ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:54**

**Generated On: 20 Jul 2016 16:57:04**

---

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? A lot ☐

---

12. Did you enjoy smoking? Little ☐

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Questionnaire on smoking urges (QSU)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:54**

**Generated On: 20 Jul 2016 16:57:04**

|  |   |
|--|---|
| Type   | QSU                                     |
| Date of Birth  | (b) (6)                                 |
| Date of assessment<br>DD/MMM/YYYY                                | 2014 MAR 11                             |
| Time of assessment<br>hour:min 24-hour clock                     | 20:01                                   |
| Assessment Status  | Completed <input type="radio"/>         |
| 1. I have a desire for a cigarette right now                     | Disagree <input type="radio"/>          |
| 2. Nothing would be better than smoking a cigarette<br>right now | Disagree <input type="radio"/>          |
| 3. If it were possible I would probably smoke now                | 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                           | Disagree <input type="radio"/>          |
| 6. I have an urge for a cigarette                                | Disagree <input type="radio"/>          |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Questionnaire on smoking urges (QSU)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:54**

**Generated On: 20 Jul 2016 16:57:04**

---

7. A cigarette would taste good now Do not agree or disagree ☐

---

8. I would do almost anything for a cigarette now Strongly disagree ☐

---

9. Smoking would make me less depressed Strongly disagree ☐

---

10. I am going to smoke as soon as possible Strongly disagree ☐

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:55**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:55**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112450002136    |
| Analyte                   | HPMA              |
| Sample type               | URINE             |
| Result                    | 330               |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 3                 |
| Celerion Study Number     | AA99128-03        |
| Date of Collection        | 2014-MAR-11       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 3                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:55**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

---

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:55**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112450002136    |
| Analyte                   | CEMA              |
| Sample type               | URINE             |
| Result                    | 13.3              |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 3                 |
| Celerion Study Number     | AA99128-03        |
| Date of Collection        | 2014-MAR-11       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 3                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:55**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

---

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:55**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112450002136    |
| Analyte                   | HBMA              |
| Sample type               | URINE             |
| Result                    | 263               |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 3                 |
| Celerion Study Number     | AA99128-03        |
| Date of Collection        | 2014-MAR-11       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 3                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:55**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

---

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (NNN, NNAL)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:54**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

URINE

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (NNN, NNAL) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:54**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112460002547    |
| Analyte                   | NNAL              |
| Sample type               | URINE             |
| Result                    | 24.8              |
| Result Unit               | PG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 3                 |
| Celerion Study Number     | AA99128-04        |
| Date of Collection        | 2014-MAR-11       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 3                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (NNN, NNAL) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:54**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

---

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (NNN, NNAL) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:54**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112460002547    |
| Analyte                   | NNN               |
| Sample type               | URINE             |
| Result                    | 0.452             |
| Result Unit               | PG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 3                 |
| Celerion Study Number     | AA99128-04        |
| Date of Collection        | 2014-MAR-11       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 3                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (NNN, NNAL) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:54**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

---

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (HEMA)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:55**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (HEMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:55**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112470001271    |
| Analyte                   | HEMA              |
| Sample type               | URINE             |
| Result                    | 0.995             |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 3                 |
| Celerion Study Number     | AA99128-05        |
| Date of Collection        | 2014-MAR-11       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 3                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (HEMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:55**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

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4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:55**

**Generated On: 20 Jul 2016 16:57:04**

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Sample type

URINE

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:55**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112480000666    |
| Analyte                   | COT               |
| Sample type               | URINE             |
| Result                    | 1370              |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 3                 |
| Celerion Study Number     | AA99128-06        |
| Date of Collection        | 2014-MAR-12       |
| Timepoint-minutes         |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:55**

**Generated On: 20 Jul 2016 16:57:04**

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|                 |   |
|-----------------|---|
| Urine Start Day | 3 |
|-----------------|---|

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|               |   |
|---------------|---|
| Urine End Day | 4 |
|---------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:55**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112480000666    |
| Analyte                   | COT-GLUC          |
| Sample type               | URINE             |
| Result                    | 1860              |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 3                 |
| Celerion Study Number     | AA99128-06        |
| Date of Collection        | 2014-MAR-12       |
| Timepoint-minutes         |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:55**

**Generated On: 20 Jul 2016 16:57:04**

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|                 |   |
|-----------------|---|
| Urine Start Day | 3 |
|-----------------|---|

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|               |   |
|---------------|---|
| Urine End Day | 4 |
|---------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:55**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112480000666    |
| Analyte                   | NIC               |
| Sample type               | URINE             |
| Result                    | 387               |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 3                 |
| Celerion Study Number     | AA99128-06        |
| Date of Collection        | 2014-MAR-12       |
| Timepoint-minutes         |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:55**

**Generated On: 20 Jul 2016 16:57:04**

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|                 |   |
|-----------------|---|
| Urine Start Day | 3 |
|-----------------|---|

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|               |   |
|---------------|---|
| Urine End Day | 4 |
|---------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:55**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112480000666    |
| Analyte                   | NIC-GLUC          |
| Sample type               | URINE             |
| Result                    | 384               |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 3                 |
| Celerion Study Number     | AA99128-06        |
| Date of Collection        | 2014-MAR-12       |
| Timepoint-minutes         |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:55**

**Generated On: 20 Jul 2016 16:57:04**

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|                 |   |
|-----------------|---|
| Urine Start Day | 3 |
|-----------------|---|

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|               |   |
|---------------|---|
| Urine End Day | 4 |
|---------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(5)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:55**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112480000666    |
| Analyte                   | THCOT             |
| Sample type               | URINE             |
| Result                    | 2510              |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 3                 |
| Celerion Study Number     | AA99128-06        |
| Date of Collection        | 2014-MAR-12       |
| Timepoint-minutes         |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(5)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:55**

**Generated On: 20 Jul 2016 16:57:04**

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|                 |   |
|-----------------|---|
| Urine Start Day | 3 |
|-----------------|---|

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|               |   |
|---------------|---|
| Urine End Day | 4 |
|---------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(6)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:55**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112480000666    |
| Analyte                   | THCOT-GLUC        |
| Sample type               | URINE             |
| Result                    | 1020              |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 3                 |
| Celerion Study Number     | AA99128-06        |
| Date of Collection        | 2014-MAR-12       |
| Timepoint-minutes         |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(6)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:55**

**Generated On: 20 Jul 2016 16:57:04**

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|                 |   |
|-----------------|---|
| Urine Start Day | 3 |
|-----------------|---|

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|               |   |
|---------------|---|
| Urine End Day | 4 |
|---------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (3-OH BaP)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:56**

**Generated On: 20 Jul 2016 16:57:04**

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Sample type

URINE

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (3-OH BaP) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:56**

**Generated On: 20 Jul 2016 16:57:04**

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|                |                |
|----------------|----------------|
| Sample Barcode | 05112490001271 |
|----------------|----------------|

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|         |          |
|---------|----------|
| Analyte | 3-OH BAP |
|---------|----------|

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|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

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|        |            |
|--------|------------|
| Result | BLQ<(25.0) |
|--------|------------|

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|             |       |
|-------------|-------|
| Result Unit | FG/ML |
|-------------|-------|

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|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

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|                |                   |
|----------------|-------------------|
| Sample comment | ANALYZED IN ERROR |
|----------------|-------------------|

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|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

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|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

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|              |   |
|--------------|---|
| Day of Visit | 3 |
|--------------|---|

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|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-07 |
|-----------------------|------------|

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|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-11 |
|--------------------|-------------|

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|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

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|                 |   |
|-----------------|---|
| Urine Start Day | 3 |
|-----------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (3-OH BaP) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:56**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

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4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:56**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

URINE

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:56**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112510001293    |
| Analyte                   | 1-NA              |
| Sample type               | URINE             |
| Result                    | 6.16              |
| Result Unit               | PG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 3                 |
| Celerion Study Number     | AA99128-09        |
| Date of Collection        | 2014-MAR-11       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 3                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:56**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

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4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:56**

**Generated On: 20 Jul 2016 16:57:04**

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|                |                |
|----------------|----------------|
| Sample Barcode | 05112510001293 |
|----------------|----------------|

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|         |      |
|---------|------|
| Analyte | 2-NA |
|---------|------|

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|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

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|        |            |
|--------|------------|
| Result | BLQ<(2.50) |
|--------|------------|

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|             |       |
|-------------|-------|
| Result Unit | PG/ML |
|-------------|-------|

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|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

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|                |                   |
|----------------|-------------------|
| Sample comment | ANALYZED IN ERROR |
|----------------|-------------------|

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|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

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|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

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|              |   |
|--------------|---|
| Day of Visit | 3 |
|--------------|---|

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|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-09 |
|-----------------------|------------|

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|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-11 |
|--------------------|-------------|

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|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

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|                 |   |
|-----------------|---|
| Urine Start Day | 3 |
|-----------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:56**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

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4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:56**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112510001293    |
| Analyte                   | 4-ABP             |
| Sample type               | URINE             |
| Result                    | 1.72              |
| Result Unit               | PG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 3                 |
| Celerion Study Number     | AA99128-09        |
| Date of Collection        | 2014-MAR-11       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 3                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:56**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

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4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:56**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112510001293    |
| Analyte                   | O-TOL             |
| Sample type               | URINE             |
| Result                    | BLQ<(50.0)        |
| Result Unit               | PG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 3                 |
| Celerion Study Number     | AA99128-09        |
| Date of Collection        | 2014-MAR-11       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 3                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:56**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

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4



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (1-OHP)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:56**

**Generated On: 20 Jul 2016 16:57:04**

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Sample type

URINE

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (1-OHP) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:56**

**Generated On: 20 Jul 2016 16:57:04**

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|                |                |
|----------------|----------------|
| Sample Barcode | 05115190001568 |
|----------------|----------------|

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|         |       |
|---------|-------|
| Analyte | 1-OHP |
|---------|-------|

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|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

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|        |   |
|--------|---|
| Result | . |
|--------|---|

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|             |       |
|-------------|-------|
| Result Unit | PG/ML |
|-------------|-------|

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|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | NOT ANALYZED IN ERROR |
|----------------|-----------------------|

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|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

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|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 3 |
|--------------|---|

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|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99598-03 |
|-----------------------|------------|

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|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-11 |
|--------------------|-------------|

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|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

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|                 |   |
|-----------------|---|
| Urine Start Day | 3 |
|-----------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (1-OHP) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:56**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

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4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (SPMA, SBMA)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:55**

**Generated On: 20 Jul 2016 16:57:04**

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Sample type

URINE

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (SPMA, SBMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:55**

**Generated On: 20 Jul 2016 16:57:04**

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|                |                |
|----------------|----------------|
| Sample Barcode | 05115170001546 |
|----------------|----------------|

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|         |      |
|---------|------|
| Analyte | SBMA |
|---------|------|

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|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

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|        |   |
|--------|---|
| Result | . |
|--------|---|

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|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

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|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

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|                |                       |
|----------------|-----------------------|
| Sample comment | NOT ANALYZED IN ERROR |
|----------------|-----------------------|

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|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 3 |
|--------------|---|

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|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99598-01 |
|-----------------------|------------|

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|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-11 |
|--------------------|-------------|

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|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

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|                 |   |
|-----------------|---|
| Urine Start Day | 3 |
|-----------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (SPMA, SBMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:55**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

4

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (SPMA, SBMA) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:55**

**Generated On: 20 Jul 2016 16:57:04**

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|                |                |
|----------------|----------------|
| Sample Barcode | 05115170001546 |
|----------------|----------------|

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|         |      |
|---------|------|
| Analyte | SPMA |
|---------|------|

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|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

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|        |   |
|--------|---|
| Result | . |
|--------|---|

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|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

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|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

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|                |                       |
|----------------|-----------------------|
| Sample comment | NOT ANALYZED IN ERROR |
|----------------|-----------------------|

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|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

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|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 3 |
|--------------|---|

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|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99598-01 |
|-----------------------|------------|

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|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-11 |
|--------------------|-------------|

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|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

---

|                 |   |
|-----------------|---|
| Urine Start Day | 3 |
|-----------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (SPMA, SBMA) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:55**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

---

4



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (MHBMA)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:55**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (MHBMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:55**

**Generated On: 20 Jul 2016 16:57:04**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05115180001568 |
|----------------|----------------|

---

|         |       |
|---------|-------|
| Analyte | MHBMA |
|---------|-------|

---

|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | NOT ANALYZED IN ERROR |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 3 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99598-02 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-11 |
|--------------------|-------------|

---

|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

---

|                 |   |
|-----------------|---|
| Urine Start Day | 3 |
|-----------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (MHBMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:55**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

---

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (Creatinine)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:56**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (Creatinine) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:56**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05115160001271        |
| Analyte                   | CREATININE            |
| Sample type               | URINE                 |
| Result                    | 109                   |
| Result Unit               | MG/DL                 |
| Lab Status                | OK                    |
| 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-MAR-11           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 3                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Urine (Creatinine) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:56**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

---

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Plasma (Nic, Cot, tHCot)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:55**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

PLASMA

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:55**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112430001619    |
| Analyte                   | COT               |
| Sample type               | PLASMA            |
| Result                    | 277               |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 3                 |
| Celerion Study Number     | AA99128-01        |
| Date of Collection        | 2014-MAR-11       |
| Timepoint-minutes         | 0                 |
| Urine Start Day           |                   |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:55**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

3

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:55**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112430001619    |
| Analyte                   | NIC               |
| Sample type               | PLASMA            |
| Result                    | 18.7              |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 3                 |
| Celerion Study Number     | AA99128-01        |
| Date of Collection        | 2014-MAR-11       |
| Timepoint-minutes         | 0                 |
| Urine Start Day           |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 3**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:55**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

3

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Date of Visit**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:56**

**Generated On: 20 Jul 2016 16:57:04**

---

Date of Visit

12 MAR 2014  
DD/MMM/YYYY

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Vital Signs**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:56**

**Generated On: 20 Jul 2016 16:57:04**

---

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 10:15  
hour:min 24-hour clock

---

Pulse rate 59  
beats per minute

---

Respiratory rate 12  
breaths per minute

---

Blood Pressure (systolic) 121  
mmHg

---

Blood Pressure (diastolic) 73  
mmHg

---

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Socio-Economic Status**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:56**

**Generated On: 20 Jul 2016 16:57:04**

---

Was paper questionnaire used? Yes ☒

---

Reason not done \_\_\_\_\_

---

Date 12 MAR 2014  
DD/MMM/YYYY

---

Time 07:17  
hour:min 24-hour clock

---

Q1. What is the highest level of education you have completed? Some College ☒

---

Q2. What is your current occupational status? Looking for work, unemployed ☒

---

SPECIFY \_\_\_\_\_

---

Q3. How many people are currently living in your household, including yourself? 03

---

Q4. Of these people, how many are children? 01

---

Q5. Of these people, how many are adults? 02

---

Q6. Of the adults, how many bring income into the household? 01

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Socio-Economic Status**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:56**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Day 4**

**Form: Plasma Nicotine Sample**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:56**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

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

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 12 MAR 2014 |
|---------------------|-------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 20:13 |
|--------------------------------|-------|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Plasma Cotinine Sample**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:56**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

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

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 12 MAR 2014 |
|---------------------|-------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 20:13 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: CoHb Blood Sample**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:56**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

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

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 12 MAR 2014 |
|---------------------|-------------|

---

|           |  |
|-----------|--|
| Timepoint | 20:00 - 21:30 <input checked="" type="radio"/> |
|-----------|--|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 20:13 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: CO Breath Test (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:56**

**Generated On: 20 Jul 2016 16:57:04**

---

|                     |       |
|---------------------|-------|
| 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 | 06:35 |
|---|-------|

---

|             |   |
|-------------|---|
| Result(ppm) | 1 |
|-------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: CO Breath Test (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:56**

**Generated On: 20 Jul 2016 16:57:04**

---

|                     |       |
|---------------------|-------|
| 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 | 12:18 |
|---|-------|

---

|             |   |
|-------------|---|
| Result(ppm) | 2 |
|-------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: CO Breath Test (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:56**

**Generated On: 20 Jul 2016 16:57:04**

---

|                     |       |
|---------------------|-------|
| 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 | 16:13 |
|---|-------|

---

|             |   |
|-------------|---|
| Result(ppm) | 2 |
|-------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: CO Breath Test (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:56**

**Generated On: 20 Jul 2016 16:57:04**

---

|                     |       |
|---------------------|-------|
| 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 | 20:18 |
|---|-------|

---

|             |   |
|-------------|---|
| Result(ppm) | 0 |
|-------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: 24 hour urine collections**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:56**

**Generated On: 20 Jul 2016 16:57:04**

---

|            |                        |
|------------|------------------------|
| Start Time | 06:02                  |
|            | hour:min 24-hour clock |

---

|          |             |
|----------|-------------|
| End Date | 13 MAR 2014 |
|          | DD/MMM/YYYY |

---

|          |                        |
|----------|------------------------|
| End Time | 06:12                  |
|          | hour:min 24-hour clock |

---

|        |     |
|--------|-----|
| Volume | 998 |
|        | mL  |

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Sample Urine Collection**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:56**

**Generated On: 20 Jul 2016 16:57:04**

---

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?

11

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:57**

**Generated On: 20 Jul 2016 16:57:04**

---

Date of Birth

(b) (6)

---

Date of assessment  
DD/MMM/YYYY

2014 MAR 12  
DD/MMM/YYYY

---

Time of assessment

06:07  
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?

Mild ☐

4. Desire or craving to smoke

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:57**

**Generated On: 20 Jul 2016 16:57:04**

---

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? None ☐

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? None ☐

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: 1194**

**Folder: Day 4**

**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:57**

**Generated On: 20 Jul 2016 16:57:04**

---

How have you been feeling over the past 24 hours?

Slight ☒

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: 1194**

**Folder: Day 4**

**Form: Cough Assessment**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:57**

**Generated On: 20 Jul 2016 16:57:04**

---

Date of Birth

(b) (6)

---

Date of assessment  
DD/MMM/YYYY

2014 MAR 12  
DD/MMM/YYYY

---

Time of assessment

06:06  
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: 1194**

**Folder: Day 4**

**Form: Lab\_BU\_COHB (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:57**

**Generated On: 20 Jul 2016 16:57:04**

|                               |                    |
|-------------------------------|--------------------|
| Sample Barcode                | 05115150001271     |
| Analyte                       | CARBOXYHEMOGLOBIN  |
| Sample type                   | BLOOD              |
| Result                        | 2.60               |
| Result Unit                   | %                  |
| Lab Status                    | OK                 |
| Sample comment                | .                  |
| 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-MAR-12        |
| Timepoint-minutes             |                    |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Lab\_BU\_COHB (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:57**

**Generated On: 20 Jul 2016 16:57:04**

---

Start Day (24 hour urine only) \_\_\_\_\_

---

End Day (24 hour Urine Only) \_\_\_\_\_

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:57**

**Generated On: 20 Jul 2016 16:57:04**

---

Date of Birth

(b) (6)

---

Date of assessment

2014 MAR 12

DD/MMM/YYYY

DD/MMM/YYYY

---

Time of assessment

20:03

hour:min 24-hour clock

---

Assessment Status

Completed ☒

---

1. Was smoking satisfying?

Moderately ☒

---

2. Did cigarettes taste good?

Very little ☒

---

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?

Very little ☒

---

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: 1194**

**Folder: Day 4**

**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:57**

**Generated On: 20 Jul 2016 16:57:04**

---

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? Very little ☐

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Human Smoking Topography Questionnaire**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:57**

**Generated On: 20 Jul 2016 16:57:04**

---

|      |  |
|------|--|
| Type | HUMAN SMOKING<br>TOPOGRAPHY<br>QUESTIONNAIRE |
|------|--|

---

|                               |                                      |
|-------------------------------|--------------------------------------|
| Was paper questionnaire used? | Yes <input checked="" type="radio"/> |
|-------------------------------|--------------------------------------|

---

|                 |  |
|-----------------|--|
| Reason not done |  |
|-----------------|--|

---

|                    |                            |
|--------------------|----------------------------|
| Date of assessment | 12 MAR 2014<br>DD/MMM/YYYY |
|--------------------|----------------------------|

---

|                    |                                 |
|--------------------|---------------------------------|
| Time of assessment | 20:21<br>hour:min 24-hour clock |
|--------------------|---------------------------------|

---

How do you agree with the following sentences/affirmations :

---

|   |   |
|---|---|
| 1. The smoking of the conventional cigarettes/products<br>is different with the device. | Strongly agree <input checked="" type="radio"/> |
|---|---|

---

|   |  |
|---|--|
| If you agree or strongly agree, please describe : | NOT THE SAME TYPE OF PULL<br>AS A CONVENTIONAL<br>CIGARETTE. ALSO DOESN'T<br>LAST AS LONG. |
|---|--|

---

|  |   |
|--|---|
| 2. You enjoy smoking with the device as much as<br>without it. | Strongly disagree <input type="radio"/> |
|--|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Human Smoking Topography Questionnaire**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:57**

**Generated On: 20 Jul 2016 16:57:04**

---

If you disagree or strongly disagree, please describe : SMOKING WITH THE DEVICE  
IS CUMBERSOME. IT WOULD  
BE MUCH BETTER IF IT WAS  
MORE READILY TO SMOKE  
WITHOUT SO MUCH SET UP.

---

3. The taste of the conventional cigarettes/products is different with the device. Neither agree nor disagree ☒

---

If you agree or strongly agree, please describe : \_\_\_\_\_

---

4. The device is easy to use. Neither agree nor disagree ☒

---

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 : TOO TIME CONSUMING. MOST  
PEOPLE WOULD PREFER TO  
BE ABLE TO PICK UP THE  
DEVICE AND JUST START  
SMOKING.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Questionnaire on smoking urges (QSU)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:57**

**Generated On: 20 Jul 2016 16:57:04**

|   |   |
|---|---|
| Type  | QSU                                     |
| Date of Birth   | (b) (6)                                 |
| Date of assessment  | 2014 MAR 12                             |
| DD/MMM/YYYY   |   |
| Time of assessment  | 20:02                                   |
| hour:min 24-hour clock  |   |
| Assessment Status   | Completed <input type="radio"/>         |
| 1. I have a desire for a cigarette right now                  | Disagree <input type="radio"/>          |
| 2. Nothing would be better than smoking a cigarette right now | Strongly disagree <input type="radio"/> |
| 3. If it were possible I would probably smoke now             | 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                        | Disagree <input type="radio"/>          |
| 6. I have an urge for a cigarette                             | Disagree <input type="radio"/>          |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Questionnaire on smoking urges (QSU)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:57**

**Generated On: 20 Jul 2016 16:57:04**

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7. A cigarette would taste good now Strongly disagree ☐

---

8. I would do almost anything for a cigarette now Strongly disagree ☐

---

9. Smoking would make me less depressed Strongly disagree ☐

---

10. I am going to smoke as soon as possible Disagree ☐

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:58**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (CEMA, HPMa, HBMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:58**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112450002137    |
| Analyte                   | HPMA              |
| Sample type               | URINE             |
| Result                    | 663               |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 4                 |
| Celerion Study Number     | AA99128-03        |
| Date of Collection        | 2014-MAR-12       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 4                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:58**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

5

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:58**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112450002137    |
| Analyte                   | CEMA              |
| Sample type               | URINE             |
| Result                    | 24.1              |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 4                 |
| Celerion Study Number     | AA99128-03        |
| Date of Collection        | 2014-MAR-12       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 4                 |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:58**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

---

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (CEMA, HPMa, HBMA) (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:58**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112450002137    |
| Analyte                   | HBMA              |
| Sample type               | URINE             |
| Result                    | 578               |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 4                 |
| Celerion Study Number     | AA99128-03        |
| Date of Collection        | 2014-MAR-12       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 4                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:58**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

5

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (NNN, NNAL)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:57**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

URINE

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (NNN, NNAL) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:57**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112460002548    |
| Analyte                   | NNAL              |
| Sample type               | URINE             |
| Result                    | 42.1              |
| Result Unit               | PG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 4                 |
| Celerion Study Number     | AA99128-04        |
| Date of Collection        | 2014-MAR-12       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 4                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (NNN, NNAL) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:57**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

5

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (NNN, NNAL) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:57**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112460002548    |
| Analyte                   | NNN               |
| Sample type               | URINE             |
| Result                    | 0.418             |
| Result Unit               | PG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 4                 |
| Celerion Study Number     | AA99128-04        |
| Date of Collection        | 2014-MAR-12       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 4                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (NNN, NNAL) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:57**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

5

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (HEMA)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:57**

**Generated On: 20 Jul 2016 16:57:04**

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Sample type

URINE

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (HEMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:57**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112470001272    |
| Analyte                   | HEMA              |
| Sample type               | URINE             |
| Result                    | 1.55              |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 4                 |
| Celerion Study Number     | AA99128-05        |
| Date of Collection        | 2014-MAR-12       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 4                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (HEMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:57**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

5

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:58**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:58**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112480000667    |
| Analyte                   | COT               |
| Sample type               | URINE             |
| Result                    | 1700              |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 4                 |
| Celerion Study Number     | AA99128-06        |
| Date of Collection        | 2014-MAR-13       |
| Timepoint-minutes         |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:58**

**Generated On: 20 Jul 2016 16:57:04**

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|                 |   |
|-----------------|---|
| Urine Start Day | 4 |
|-----------------|---|

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|               |   |
|---------------|---|
| Urine End Day | 5 |
|---------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:58**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112480000667    |
| Analyte                   | COT-GLUC          |
| Sample type               | URINE             |
| Result                    | 4130              |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 4                 |
| Celerion Study Number     | AA99128-06        |
| Date of Collection        | 2014-MAR-13       |
| Timepoint-minutes         |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:58**

**Generated On: 20 Jul 2016 16:57:04**

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|                 |   |
|-----------------|---|
| Urine Start Day | 4 |
|-----------------|---|

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|               |   |
|---------------|---|
| Urine End Day | 5 |
|---------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:58**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112480000667    |
| Analyte                   | NIC               |
| Sample type               | URINE             |
| Result                    | 548               |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 4                 |
| Celerion Study Number     | AA99128-06        |
| Date of Collection        | 2014-MAR-13       |
| Timepoint-minutes         |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:58**

**Generated On: 20 Jul 2016 16:57:04**

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|                 |   |
|-----------------|---|
| Urine Start Day | 4 |
|-----------------|---|

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|               |   |
|---------------|---|
| Urine End Day | 5 |
|---------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:58**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112480000667    |
| Analyte                   | NIC-GLUC          |
| Sample type               | URINE             |
| Result                    | 680               |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 4                 |
| Celerion Study Number     | AA99128-06        |
| Date of Collection        | 2014-MAR-13       |
| Timepoint-minutes         |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:58**

**Generated On: 20 Jul 2016 16:57:04**

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|                 |   |
|-----------------|---|
| Urine Start Day | 4 |
|-----------------|---|

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|               |   |
|---------------|---|
| Urine End Day | 5 |
|---------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(5)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:58**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112480000667    |
| Analyte                   | THCOT             |
| Sample type               | URINE             |
| Result                    | 4660              |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 4                 |
| Celerion Study Number     | AA99128-06        |
| Date of Collection        | 2014-MAR-13       |
| Timepoint-minutes         |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(5)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:58**

**Generated On: 20 Jul 2016 16:57:04**

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|                 |   |
|-----------------|---|
| Urine Start Day | 4 |
|-----------------|---|

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|               |   |
|---------------|---|
| Urine End Day | 5 |
|---------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(6)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:58**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112480000667    |
| Analyte                   | THCOT-GLUC        |
| Sample type               | URINE             |
| Result                    | 2420              |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 4                 |
| Celerion Study Number     | AA99128-06        |
| Date of Collection        | 2014-MAR-13       |
| Timepoint-minutes         |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(6)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:58**

**Generated On: 20 Jul 2016 16:57:04**

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|                 |   |
|-----------------|---|
| Urine Start Day | 4 |
|-----------------|---|

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|               |   |
|---------------|---|
| Urine End Day | 5 |
|---------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (3-OH BaP)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:58**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (3-OH BaP) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:58**

**Generated On: 20 Jul 2016 16:57:04**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05112490001272 |
|----------------|----------------|

---

|         |          |
|---------|----------|
| Analyte | 3-OH BAP |
|---------|----------|

---

|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

---

|        |            |
|--------|------------|
| Result | BLQ<(25.0) |
|--------|------------|

---

|             |       |
|-------------|-------|
| Result Unit | FG/ML |
|-------------|-------|

---

|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

---

|                |                   |
|----------------|-------------------|
| Sample comment | ANALYZED IN ERROR |
|----------------|-------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 4 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-07 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-12 |
|--------------------|-------------|

---

|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

---

|                 |   |
|-----------------|---|
| Urine Start Day | 4 |
|-----------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (3-OH BaP) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:58**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

5

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:58**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:58**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112510001294    |
| Analyte                   | 1-NA              |
| Sample type               | URINE             |
| Result                    | 14.0              |
| Result Unit               | PG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 4                 |
| Celerion Study Number     | AA99128-09        |
| Date of Collection        | 2014-MAR-12       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 4                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:58**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

---

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:58**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112510001294    |
| Analyte                   | 2-NA              |
| Sample type               | URINE             |
| Result                    | 5.97              |
| Result Unit               | PG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 4                 |
| Celerion Study Number     | AA99128-09        |
| Date of Collection        | 2014-MAR-12       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 4                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:58**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

---

5



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:58**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112510001294    |
| Analyte                   | 4-ABP             |
| Sample type               | URINE             |
| Result                    | 4.16              |
| Result Unit               | PG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 4                 |
| Celerion Study Number     | AA99128-09        |
| Date of Collection        | 2014-MAR-12       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 4                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:58**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

---

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:58**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112510001294    |
| Analyte                   | O-TOL             |
| Sample type               | URINE             |
| Result                    | 96.3              |
| Result Unit               | PG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 4                 |
| Celerion Study Number     | AA99128-09        |
| Date of Collection        | 2014-MAR-12       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 4                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:58**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

---

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (1-OHP)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:59**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

URINE

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (1-OHP) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:59**

**Generated On: 20 Jul 2016 16:57:04**

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|                |                |
|----------------|----------------|
| Sample Barcode | 05115190001569 |
|----------------|----------------|

---

|         |       |
|---------|-------|
| Analyte | 1-OHP |
|---------|-------|

---

|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | PG/ML |
|-------------|-------|

---

|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | NOT ANALYZED IN ERROR |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 4 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99598-03 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-12 |
|--------------------|-------------|

---

|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

---

|                 |   |
|-----------------|---|
| Urine Start Day | 4 |
|-----------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (1-OHP) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:59**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

5

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (SPMA, SBMA)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:57**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

URINE

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (SPMA, SBMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:57**

**Generated On: 20 Jul 2016 16:57:04**

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|                |                |
|----------------|----------------|
| Sample Barcode | 05115170001547 |
|----------------|----------------|

---

|         |      |
|---------|------|
| Analyte | SBMA |
|---------|------|

---

|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | NOT ANALYZED IN ERROR |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 4 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99598-01 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-12 |
|--------------------|-------------|

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|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

---

|                 |   |
|-----------------|---|
| Urine Start Day | 4 |
|-----------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (SPMA, SBMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:57**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

5

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (SPMA, SBMA) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:57**

**Generated On: 20 Jul 2016 16:57:04**

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|                |                |
|----------------|----------------|
| Sample Barcode | 05115170001547 |
|----------------|----------------|

---

|         |      |
|---------|------|
| Analyte | SPMA |
|---------|------|

---

|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | NOT ANALYZED IN ERROR |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 4 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99598-01 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-12 |
|--------------------|-------------|

---

|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

---

|                 |   |
|-----------------|---|
| Urine Start Day | 4 |
|-----------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (SPMA, SBMA) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:57**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

5

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (MHBMA)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:57**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

URINE

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (MHBMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:57**

**Generated On: 20 Jul 2016 16:57:04**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05115180001569 |
|----------------|----------------|

---

|         |       |
|---------|-------|
| Analyte | MHBMA |
|---------|-------|

---

|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | NOT ANALYZED IN ERROR |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 4 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99598-02 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-12 |
|--------------------|-------------|

---

|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

---

|                 |   |
|-----------------|---|
| Urine Start Day | 4 |
|-----------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (MHBMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:57**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

5

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (Creatinine)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:59**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

URINE

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (Creatinine) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:59**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05115160001272        |
| Analyte                   | CREATININE            |
| Sample type               | URINE                 |
| Result                    | 206                   |
| Result Unit               | MG/DL                 |
| Lab Status                | OK                    |
| 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-MAR-12           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 4                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Urine (Creatinine) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:59**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

---

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Plasma (Nic, Cot, tHCot)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:57**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

PLASMA

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:57**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112430001620    |
| Analyte                   | COT               |
| Sample type               | PLASMA            |
| Result                    | 252               |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 4                 |
| Celerion Study Number     | AA99128-01        |
| Date of Collection        | 2014-MAR-12       |
| Timepoint-minutes         | 0                 |
| Urine Start Day           |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:57**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

4

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:57**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112430001620    |
| Analyte                   | NIC               |
| Sample type               | PLASMA            |
| Result                    | 14.7              |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 4                 |
| Celerion Study Number     | AA99128-01        |
| Date of Collection        | 2014-MAR-12       |
| Timepoint-minutes         | 0                 |
| Urine Start Day           |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 4**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:57**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

4

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Date of Visit**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:07**

**Generated On: 20 Jul 2016 16:57:04**

---

Date of Visit

13 MAR 2014  
DD/MMM/YYYY

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Vital Signs**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:07**

**Generated On: 20 Jul 2016 16:57:04**

---

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

09:27  
hour:min 24-hour clock

---

Pulse rate

63  
beats per minute

---

Respiratory rate

16  
breaths per minute

---

Blood Pressure (systolic)

124  
mmHg

---

Blood Pressure (diastolic)

72  
mmHg

---

Vital Signs Position of Subject

Supine ☒

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Plasma Nicotine Samples <Day 5> (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:12**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

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

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 13 MAR 2014 |
|---------------------|-------------|

---

|                |   |
|----------------|---|
| Scheduled Time | T0 -15 min <input checked="" type="radio"/> |
|----------------|---|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 06:33 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Plasma Nicotine Samples <Day 5> (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:12**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

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

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 13 MAR 2014 |
|---------------------|-------------|

---

|                |                                     |
|----------------|-------------------------------------|
| Scheduled Time | T1 <input checked="" type="radio"/> |
|----------------|-------------------------------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 08:39 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Plasma Nicotine Samples <Day 5> (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:12**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

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

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 13 MAR 2014 |
|---------------------|-------------|

---

|                |                                     |
|----------------|-------------------------------------|
| Scheduled Time | T2 <input checked="" type="radio"/> |
|----------------|-------------------------------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 10:38 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Plasma Nicotine Samples <Day 5> (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:12**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

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

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 13 MAR 2014 |
|---------------------|-------------|

---

|                |                                     |
|----------------|-------------------------------------|
| Scheduled Time | T3 <input checked="" type="radio"/> |
|----------------|-------------------------------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 12:38 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Plasma Nicotine Samples <Day 5> (5)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:12**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

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

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 13 MAR 2014 |
|---------------------|-------------|

---

|                |                                     |
|----------------|-------------------------------------|
| Scheduled Time | T4 <input checked="" type="radio"/> |
|----------------|-------------------------------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 14:38 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Plasma Nicotine Samples <Day 5> (6)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:12**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

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

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 13 MAR 2014 |
|---------------------|-------------|

---

|                |                                     |
|----------------|-------------------------------------|
| Scheduled Time | T5 <input checked="" type="radio"/> |
|----------------|-------------------------------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 16:38 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Plasma Nicotine Samples <Day 5> (7)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:12**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

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

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 13 MAR 2014 |
|---------------------|-------------|

---

|                |                                     |
|----------------|-------------------------------------|
| Scheduled Time | T6 <input checked="" type="radio"/> |
|----------------|-------------------------------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 18:38 |
|--------------------------------|-------|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Plasma Nicotine Samples <Day 5> (8)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:12**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

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

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 13 MAR 2014 |
|---------------------|-------------|

---

|                |                                     |
|----------------|-------------------------------------|
| Scheduled Time | T7 <input checked="" type="radio"/> |
|----------------|-------------------------------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 20:40 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Plasma Nicotine Samples <Day 5> (9)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:12**

**Generated On: 20 Jul 2016 16:57:04**

---

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

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

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|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 13 MAR 2014 |
|---------------------|-------------|

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|                |                                     |
|----------------|-------------------------------------|
| Scheduled Time | T8 <input checked="" type="radio"/> |
|----------------|-------------------------------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 22:38 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Plasma Cotinine Samples <Day 5> (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:10**

**Generated On: 20 Jul 2016 16:57:04**

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

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

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|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 13 MAR 2014 |
|---------------------|-------------|

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|                |   |
|----------------|---|
| Scheduled Time | T0 -15 min <input checked="" type="radio"/> |
|----------------|---|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 06:33 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Plasma Cotinine Samples <Day 5> (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:10**

**Generated On: 20 Jul 2016 16:57:04**

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

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

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|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 13 MAR 2014 |
|---------------------|-------------|

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|                |                                     |
|----------------|-------------------------------------|
| Scheduled Time | T1 <input checked="" type="radio"/> |
|----------------|-------------------------------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 08:39 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Plasma Cotinine Samples <Day 5> (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:10**

**Generated On: 20 Jul 2016 16:57:04**

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

---

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

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 13 MAR 2014 |
|---------------------|-------------|

---

|                |                                     |
|----------------|-------------------------------------|
| Scheduled Time | T2 <input checked="" type="radio"/> |
|----------------|-------------------------------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 10:38 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Plasma Cotinine Samples <Day 5> (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:10**

**Generated On: 20 Jul 2016 16:57:04**

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

---

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

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 13 MAR 2014 |
|---------------------|-------------|

---

|                |                                     |
|----------------|-------------------------------------|
| Scheduled Time | T3 <input checked="" type="radio"/> |
|----------------|-------------------------------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 12:38 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Plasma Cotinine Samples <Day 5> (5)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:10**

**Generated On: 20 Jul 2016 16:57:04**

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

---

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

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 13 MAR 2014 |
|---------------------|-------------|

---

|                |                                     |
|----------------|-------------------------------------|
| Scheduled Time | T4 <input checked="" type="radio"/> |
|----------------|-------------------------------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 14:38 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Plasma Cotinine Samples <Day 5> (6)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:10**

**Generated On: 20 Jul 2016 16:57:04**

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

---

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

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 13 MAR 2014 |
|---------------------|-------------|

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|                |                                     |
|----------------|-------------------------------------|
| Scheduled Time | T5 <input checked="" type="radio"/> |
|----------------|-------------------------------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 16:38 |
|--------------------------------|-------|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Plasma Cotinine Samples <Day 5> (7)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:10**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

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

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 13 MAR 2014 |
|---------------------|-------------|

---

|                |                                     |
|----------------|-------------------------------------|
| Scheduled Time | T6 <input checked="" type="radio"/> |
|----------------|-------------------------------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 18:38 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Plasma Cotinine Samples <Day 5> (8)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:10**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

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

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 13 MAR 2014 |
|---------------------|-------------|

---

|                |                                     |
|----------------|-------------------------------------|
| Scheduled Time | T7 <input checked="" type="radio"/> |
|----------------|-------------------------------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 20:40 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Plasma Cotinine Samples <Day 5> (9)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:10**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

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

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 13 MAR 2014 |
|---------------------|-------------|

---

|                |                                     |
|----------------|-------------------------------------|
| Scheduled Time | T8 <input checked="" type="radio"/> |
|----------------|-------------------------------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 22:38 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: CoHb Blood Sample(CC/THS) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:08**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

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

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 13 MAR 2014 |
|---------------------|-------------|

---

|                |   |
|----------------|---|
| Scheduled Time | Within 15 min prior to smoking <input checked="" type="radio"/> |
|----------------|---|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 06:33 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: CoHb Blood Sample(CC/THS) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:08**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

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

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 13 MAR 2014 |
|---------------------|-------------|

---

|                |  |
|----------------|--|
| Scheduled Time | 12:00 - 13:30 <input checked="" type="radio"/> |
|----------------|--|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 12:38 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: CoHb Blood Sample(CC/THS) (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:08**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

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

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 13 MAR 2014 |
|---------------------|-------------|

---

|                |  |
|----------------|--|
| Scheduled Time | 16:00 - 17:30 <input checked="" type="radio"/> |
|----------------|--|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 16:08 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: CoHb Blood Sample(CC/THS) (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:08**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

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

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 13 MAR 2014 |
|---------------------|-------------|

---

|                |  |
|----------------|--|
| Scheduled Time | 20:00 - 21:30 <input checked="" type="radio"/> |
|----------------|--|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 20:40 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: CO Breath Test (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:08**

**Generated On: 20 Jul 2016 16:57:04**

---

|                     |       |
|---------------------|-------|
| 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 | 06:39 |
|---|-------|

---

|             |   |
|-------------|---|
| Result(ppm) | 2 |
|-------------|---|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: CO Breath Test (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:08**

**Generated On: 20 Jul 2016 16:57:04**

---

|                     |       |
|---------------------|-------|
| 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 | 12:18 |
|---|-------|

---

|             |   |
|-------------|---|
| Result(ppm) | 2 |
|-------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: CO Breath Test (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:08**

**Generated On: 20 Jul 2016 16:57:04**

---

|                     |       |
|---------------------|-------|
| 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 | 16:03 |
|---|-------|

---

|             |   |
|-------------|---|
| Result(ppm) | 2 |
|-------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: CO Breath Test (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:08**

**Generated On: 20 Jul 2016 16:57:04**

---

|                     |       |
|---------------------|-------|
| 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) | 2 |
|-------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Day 5**

**Form: CYP1A2 activity Sample**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:59**

**Generated On: 20 Jul 2016 16:57:04**

---

|                                |                        |
|--------------------------------|------------------------|
| Time of caffeine tablet intake | 10:08                  |
|                                | 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    |
|--|---|--------------|
| 13 MAR 2014                              | 16:08   | Caffeine     |
| 13 MAR 2014                              | 16:08   | Paraxanthine |

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: 24 hour urine collections**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:07**

**Generated On: 20 Jul 2016 16:57:04**

---

|            |                        |
|------------|------------------------|
| Start Time | 06:12                  |
|            | hour:min 24-hour clock |

---

|          |             |
|----------|-------------|
| End Date | 14 MAR 2014 |
|          | DD/MMM/YYYY |

---

|          |                        |
|----------|------------------------|
| End Time | 06:02                  |
|          | hour:min 24-hour clock |

---

|        |      |
|--------|------|
| Volume | 1730 |
|        | mL   |

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Sample Urine Collection**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:07**

**Generated On: 20 Jul 2016 16:57:04**

---

Were samples for 24h collected?

Yes ☒

---

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

---

How many primary tubes were collected?

14

---

How many back up tubes were collected?

13

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:13**

**Generated On: 20 Jul 2016 16:57:04**

---

Date of Birth

(b) (6)

---

Date of assessment  
DD/MMM/YYYY

2014 MAR 13  
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?

None ☐

4. Desire or craving to smoke

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:13**

**Generated On: 20 Jul 2016 16:57:04**

---

How have you been feeling over the past 24 hours? None ☐

5. Difficulty concentrating

---

How have you been feeling over the past 24 hours? None ☐

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? None ☐

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: 1194**

**Folder: Day 5**

**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:13**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Day 5**

**Form: Cough Assessment**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:13**

**Generated On: 20 Jul 2016 16:57:04**

---

Date of Birth

(b) (6)

---

Date of assessment  
DD/MMM/YYYY

2014 MAR 13  
DD/MMM/YYYY

---

Time of assessment

06:03  
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: 1194**

**Folder: Day 5**

**Form: Lab\_BU\_COHB (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:14**

**Generated On: 20 Jul 2016 16:57:04**

|                               |                    |
|-------------------------------|--------------------|
| Sample Barcode                | 05115150001272     |
| Analyte                       | CARBOXYHEMOGLOBIN  |
| Sample type                   | BLOOD              |
| Result                        | 2.30               |
| Result Unit                   | %                  |
| Lab Status                    | OK                 |
| Sample comment                | .                  |
| 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-MAR-13        |
| Timepoint-minutes             |                    |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Lab\_BU\_COHB (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:14**

**Generated On: 20 Jul 2016 16:57:04**

---

Start Day (24 hour urine only) \_\_\_\_\_

---

End Day (24 hour Urine Only) \_\_\_\_\_

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Lab\_BU\_COHB (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:14**

**Generated On: 20 Jul 2016 16:57:04**

|                               |                    |
|-------------------------------|--------------------|
| Sample Barcode                | 05115150001273     |
| Analyte                       | CARBOXYHEMOGLOBIN  |
| Sample type                   | BLOOD              |
| Result                        | 2.50               |
| Result Unit                   | %                  |
| Lab Status                    | OK                 |
| Sample comment                | .                  |
| 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-MAR-13        |
| Timepoint-minutes             |                    |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Lab\_BU\_COHB (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:14**

**Generated On: 20 Jul 2016 16:57:04**

---

Start Day (24 hour urine only) \_\_\_\_\_

---

End Day (24 hour Urine Only) \_\_\_\_\_

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Lab\_BU\_COHB (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:14**

**Generated On: 20 Jul 2016 16:57:04**

|                               |                    |
|-------------------------------|--------------------|
| Sample Barcode                | 05115150001274     |
| Analyte                       | CARBOXYHEMOGLOBIN  |
| Sample type                   | BLOOD              |
| Result                        | 2.30               |
| Result Unit                   | %                  |
| Lab Status                    | OK                 |
| Sample comment                | .                  |
| 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-MAR-13        |
| Timepoint-minutes             |                    |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Lab\_BU\_COHB (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:14**

**Generated On: 20 Jul 2016 16:57:04**

---

Start Day (24 hour urine only) \_\_\_\_\_

---

End Day (24 hour Urine Only) \_\_\_\_\_

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Lab\_BU\_COHB (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:14**

**Generated On: 20 Jul 2016 16:57:04**

|                               |                    |
|-------------------------------|--------------------|
| Sample Barcode                | 05115150001275     |
| Analyte                       | CARBOXYHEMOGLOBIN  |
| Sample type                   | BLOOD              |
| Result                        | 2.70               |
| Result Unit                   | %                  |
| Lab Status                    | OK                 |
| Sample comment                | .                  |
| 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-MAR-13        |
| Timepoint-minutes             |                    |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Lab\_BU\_COHB (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:14**

**Generated On: 20 Jul 2016 16:57:04**

---

Start Day (24 hour urine only)

---

End Day (24 hour Urine Only)

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:13**

**Generated On: 20 Jul 2016 16:57:04**

---

Date of Birth

(b) (6)

---

Date of assessment

2014 MAR 13

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?

Little ☒

---

3. Did you enjoy the sensation in your throat and chest?

Moderately ☒

---

4. Did smoking calm you down?

Not at all ☒

---

5. Did smoking make you feel more awake?

Not at all ☒

---

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?

Not at all ☒

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:13**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Day 5**

**Form: Behavioral Risk Factor Surveillance System Questionnaire**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:59**

**Generated On: 20 Jul 2016 16:57:04**

---

|      |  |
|------|--|
| Type | BEHAVIORAL RISK FACTOR<br>SURVEILLANCE SYSTEM<br>QUESTIONNAIRE |
|------|--|

---

|                               |                           |
|-------------------------------|---------------------------|
| Was paper questionnaire used? | Yes <input type="radio"/> |
|-------------------------------|---------------------------|

---

|                 |  |
|-----------------|--|
| Reason not done |  |
|-----------------|--|

---

|                    |                            |
|--------------------|----------------------------|
| Date of assessment | 13 MAR 2014<br>DD/MMM/YYYY |
|--------------------|----------------------------|

---

|                    |                                 |
|--------------------|---------------------------------|
| Time of assessment | 21:17<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? | Yes <input type="radio"/> |
|--|---------------------------|

---

|  |  |
|--|--|
| How long has it been since you last smoked a cigarette, even one or two puffs? | Within the past month<br>(less than 1 month ago) <input type="radio"/> |
|--|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Behavioral Risk Factor Surveillance System Questionnaire**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:59**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Day 5**

**Form: Smoking Questionnaire (SQ)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:59**

**Generated On: 20 Jul 2016 16:57:04**

---

|      |                       |
|------|-----------------------|
| Type | SMOKING QUESTIONNAIRE |
|------|-----------------------|

---

|                               |                           |
|-------------------------------|---------------------------|
| Was paper questionnaire used? | Yes <input type="radio"/> |
|-------------------------------|---------------------------|

---

|                 |       |
|-----------------|-------|
| Reason not done | <hr/> |
|-----------------|-------|

---

|                    |                            |
|--------------------|----------------------------|
| Date of assessment | 13 MAR 2014<br>DD/MMM/YYYY |
|--------------------|----------------------------|

---

|                    |                                 |
|--------------------|---------------------------------|
| Time of assessment | 21:19<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? | 18 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: 1194**

**Folder: Day 5**

**Form: Smoking Questionnaire (SQ)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:59**

**Generated On: 20 Jul 2016 16:57:04**

---

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

00 Years

---

Months

06 Months

---

Days

00 Days

---

7. What brand of cigarettes/hand-rolled tobacco did you **NEWPORT**  
predominantly smoke in the last 12 months of smoking?

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Day 5**

**Form: Smoking Questionnaire (SQ) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:59**

**Generated On: 20 Jul 2016 16:57:04**

---

|      |                       |
|------|-----------------------|
| Type | SMOKING QUESTIONNAIRE |
|------|-----------------------|

---

|                               |                           |
|-------------------------------|---------------------------|
| Was paper questionnaire used? | Yes <input type="radio"/> |
|-------------------------------|---------------------------|

---

|                 |       |
|-----------------|-------|
| Reason not done | <hr/> |
|-----------------|-------|

---

|                    |                            |
|--------------------|----------------------------|
| Date of assessment | 13 MAR 2014<br>DD/MMM/YYYY |
|--------------------|----------------------------|

---

|                    |                                 |
|--------------------|---------------------------------|
| Time of assessment | 21:19<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? | 18 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: 1194**

**Folder: Day 5**

**Form: Smoking Questionnaire (SQ) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:59**

**Generated On: 20 Jul 2016 16:57:04**

---

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

00 Years

---

Months

06 Months

---

Days

00 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: 1194**

**Folder: Day 5**

**Form: Smoking Questionnaire (SQ) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:59**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Day 5**

**Form: Smoking Questionnaire (SQ) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:59**

**Generated On: 20 Jul 2016 16:57:04**

---

|      |                       |
|------|-----------------------|
| Type | SMOKING QUESTIONNAIRE |
|------|-----------------------|

---

|                               |                           |
|-------------------------------|---------------------------|
| Was paper questionnaire used? | Yes <input type="radio"/> |
|-------------------------------|---------------------------|

---

|                 |       |
|-----------------|-------|
| Reason not done | <hr/> |
|-----------------|-------|

---

|                    |                            |
|--------------------|----------------------------|
| Date of assessment | 13 MAR 2014<br>DD/MMM/YYYY |
|--------------------|----------------------------|

---

|                    |                                 |
|--------------------|---------------------------------|
| Time of assessment | 21:19<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? | 18 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: 1194**

**Folder: Day 5**

**Form: Smoking Questionnaire (SQ) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:59**

**Generated On: 20 Jul 2016 16:57:04**

---

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

00 Years

---

Months

06 Months

---

Days

00 Days

---

7. What brand of cigarettes/hand-rolled tobacco did you **NEWPORT**  
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: 1194**

**Folder: Day 5**

**Form: Smoking Questionnaire (SQ) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:59**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Day 5**

**Form: Smoking Questionnaire (SQ) (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:59**

**Generated On: 20 Jul 2016 16:57:04**

---

|      |                       |
|------|-----------------------|
| Type | SMOKING QUESTIONNAIRE |
|------|-----------------------|

---

|                               |                           |
|-------------------------------|---------------------------|
| Was paper questionnaire used? | Yes <input type="radio"/> |
|-------------------------------|---------------------------|

---

|                 |       |
|-----------------|-------|
| Reason not done | <hr/> |
|-----------------|-------|

---

|                    |                            |
|--------------------|----------------------------|
| Date of assessment | 13 MAR 2014<br>DD/MMM/YYYY |
|--------------------|----------------------------|

---

|                    |                                 |
|--------------------|---------------------------------|
| Time of assessment | 21:19<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? | 18 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: 1194**

**Folder: Day 5**

**Form: Smoking Questionnaire (SQ) (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:59**

**Generated On: 20 Jul 2016 16:57:04**

---

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

00 Years

---

Months

06 Months

---

Days

00 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: 1194**

**Folder: Day 5**

**Form: Smoking Questionnaire (SQ) (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:59**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Day 5**

**Form: Smoking Questionnaire (SQ) (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:59**

**Generated On: 20 Jul 2016 16:57:04**

---

|      |                       |
|------|-----------------------|
| Type | SMOKING QUESTIONNAIRE |
|------|-----------------------|

---

|                               |                           |
|-------------------------------|---------------------------|
| Was paper questionnaire used? | Yes <input type="radio"/> |
|-------------------------------|---------------------------|

---

|                 |       |
|-----------------|-------|
| Reason not done | <hr/> |
|-----------------|-------|

---

|                    |                            |
|--------------------|----------------------------|
| Date of assessment | 13 MAR 2014<br>DD/MMM/YYYY |
|--------------------|----------------------------|

---

|                    |                                 |
|--------------------|---------------------------------|
| Time of assessment | 21:19<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? | 18 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: 1194**

**Folder: Day 5**

**Form: Smoking Questionnaire (SQ) (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:59**

**Generated On: 20 Jul 2016 16:57:04**

---

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

00 Years

---

Months

06 Months

---

Days

00 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: 1194**

**Folder: Day 5**

**Form: Smoking Questionnaire (SQ) (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:59**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Day 5**

**Form: Smoking Questionnaire (SQ) (5)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:59**

**Generated On: 20 Jul 2016 16:57:04**

---

|      |                       |
|------|-----------------------|
| Type | SMOKING QUESTIONNAIRE |
|------|-----------------------|

---

|                               |                           |
|-------------------------------|---------------------------|
| Was paper questionnaire used? | Yes <input type="radio"/> |
|-------------------------------|---------------------------|

---

|                 |       |
|-----------------|-------|
| Reason not done | <hr/> |
|-----------------|-------|

---

|                    |                            |
|--------------------|----------------------------|
| Date of assessment | 13 MAR 2014<br>DD/MMM/YYYY |
|--------------------|----------------------------|

---

|                    |                                 |
|--------------------|---------------------------------|
| Time of assessment | 21:19<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? | 18 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: 1194**

**Folder: Day 5**

**Form: Smoking Questionnaire (SQ) (5)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:59**

**Generated On: 20 Jul 2016 16:57:04**

---

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

00 Years

---

Months

06 Months

---

Days

00 Days

---

7. What brand of cigarettes/hand-rolled tobacco did you **NEWPORT**  
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?

None ☒

---

Manufactured Cigarettes  
per day

---

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: 1194**

**Folder: Day 5**

**Form: Smoking Questionnaire (SQ) (5)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:59**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Day 5**

**Form: Smoking Questionnaire (SQ) (6)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:59**

**Generated On: 20 Jul 2016 16:57:04**

---

|      |                       |
|------|-----------------------|
| Type | SMOKING QUESTIONNAIRE |
|------|-----------------------|

---

|                               |                           |
|-------------------------------|---------------------------|
| Was paper questionnaire used? | Yes <input type="radio"/> |
|-------------------------------|---------------------------|

---

|                 |       |
|-----------------|-------|
| Reason not done | <hr/> |
|-----------------|-------|

---

|                    |                            |
|--------------------|----------------------------|
| Date of assessment | 13 MAR 2014<br>DD/MMM/YYYY |
|--------------------|----------------------------|

---

|                    |                                 |
|--------------------|---------------------------------|
| Time of assessment | 21:19<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? | 18 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: 1194**

**Folder: Day 5**

**Form: Smoking Questionnaire (SQ) (6)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:59**

**Generated On: 20 Jul 2016 16:57:04**

---

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 \_\_\_\_\_ 00 Years

---

Months \_\_\_\_\_ 06 Months

---

Days \_\_\_\_\_ 00 Days

---

7. What brand of cigarettes/hand-rolled tobacco did you **NEWPORT**  
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? \_\_\_\_\_ None ☒

---

Manufactured Cigarettes  
per day \_\_\_\_\_

---

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: 1194**

**Folder: Day 5**

**Form: Smoking Questionnaire (SQ) (6)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:59**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Day 5**

**Form: Smoking Questionnaire (SQ) (7)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:59**

**Generated On: 20 Jul 2016 16:57:04**

---

|      |                       |
|------|-----------------------|
| Type | SMOKING QUESTIONNAIRE |
|------|-----------------------|

---

|                               |                           |
|-------------------------------|---------------------------|
| Was paper questionnaire used? | Yes <input type="radio"/> |
|-------------------------------|---------------------------|

---

|                 |       |
|-----------------|-------|
| Reason not done | <hr/> |
|-----------------|-------|

---

|                    |                            |
|--------------------|----------------------------|
| Date of assessment | 13 MAR 2014<br>DD/MMM/YYYY |
|--------------------|----------------------------|

---

|                    |                                 |
|--------------------|---------------------------------|
| Time of assessment | 21:19<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? | 18 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: 1194**

**Folder: Day 5**

**Form: Smoking Questionnaire (SQ) (7)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:59**

**Generated On: 20 Jul 2016 16:57:04**

---

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

00 Years

---

Months

06 Months

---

Days

00 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?

None ☒

---

Manufactured Cigarettes  
per day

---

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: 1194**

**Folder: Day 5**

**Form: Smoking Questionnaire (SQ) (7)**

**Data signed: (hfarmer1) 27 Mar 2015 14:34:59**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Day 5**

**Form: Supplemental Questions**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:06**

**Generated On: 20 Jul 2016 16:57:04**

---

Was paper questionnaire used?

Yes ☒

---

Reason not done

---

---

Date of Assessment

13 MAR 2014  
DD/MMM/YYYY

---

Time of assessment

21:20

---

1. How long it takes for the subject to complete the SQ

01 minutes

---

Comments (open-end)

NO COMMENTS AT THIS  
TIME.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Supplemental Questions (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:06**

**Generated On: 20 Jul 2016 16:57:04**

---

Was paper questionnaire used? Yes ☒

---

Reason not done \_\_\_\_\_

---

Date of Assessment 13 MAR 2014  
DD/MMM/YYYY

---

Time of assessment 21:20

---

1. How long it takes for the subject to complete the SQ 01 minutes

---

Question 2. Did the SQ capture your smoking behavior completely? ☒

---

Answer Yes ☒

---

Comments (open-end) NO COMMENTS AT THIS TIME.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Supplemental Questions (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:06**

**Generated On: 20 Jul 2016 16:57:04**

---

Was paper questionnaire used? Yes ☐

---

Reason not done \_\_\_\_\_

---

Date of Assessment 13 MAR 2014  
DD/MMM/YYYY

---

Time of assessment 21:20

---

1. How long it takes for the subject to complete the SQ 01 minutes

---

Question 3. Did the SQ capture your smoking behavior correctly? ☐

---

Answer Yes ☐

---

Comments (open-end) NO COMMENTS AT THIS TIME.



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Supplemental Questions (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:06**

**Generated On: 20 Jul 2016 16:57:04**

---

Was paper questionnaire used? Yes ☐

---

Reason not done \_\_\_\_\_

---

Date of Assessment 13 MAR 2014  
DD/MMM/YYYY

---

Time of assessment 21:20

---

1. How long it takes for the subject to complete the SQ 01 minutes

---

Question 4. Did the SQ capture your smoking history completely? ☐

---

Answer Yes ☐

---

Comments (open-end) NO COMMENTS AT THIS TIME.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Supplemental Questions (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:06**

**Generated On: 20 Jul 2016 16:57:04**

---

Was paper questionnaire used? Yes ☐

---

Reason not done \_\_\_\_\_

---

Date of Assessment 13 MAR 2014  
DD/MMM/YYYY

---

Time of assessment 21:20

---

1. How long it takes for the subject to complete the SQ 01 minutes

---

Question 5. Did the SQ capture your smoking history correctly? ☐

---

Answer Yes ☐

---

Comments (open-end) NO COMMENTS AT THIS TIME.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Supplemental Questions (5)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:06**

**Generated On: 20 Jul 2016 16:57:04**

---

Was paper questionnaire used? Yes ☐

---

Reason not done

---

---

Date of Assessment 13 MAR 2014  
DD/MMM/YYYY

---

---

Time of assessment 21:20

---

---

1. How long it takes for the subject to complete the SQ 01 minutes

---

---

Question 6. Was the SQ ☐  
self-explaining?

---

---

Answer Yes ☐

---

---

Comments (open-end) NO COMMENTS AT THIS  
TIME.

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Day 5**

**Form: Supplemental Questions (6)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:06**

**Generated On: 20 Jul 2016 16:57:04**

---

Was paper questionnaire used? Yes ☐

---

Reason not done \_\_\_\_\_

---

Date of Assessment 13 MAR 2014  
DD/MMM/YYYY

---

Time of assessment 21:20

---

1. How long it takes for the subject to complete the SQ 01 minutes

---

Question 7. Was the SQ easy to use? ☐

---

Answer Yes ☐

---

Comments (open-end) NO COMMENTS AT THIS  
TIME.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Questionnaire on smoking urges (QSU)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:13**

**Generated On: 20 Jul 2016 16:57:04**

|   |   |
|---|---|
| Type  | QSU                                     |
| Date of Birth   | (b) (6)                                 |
| Date of assessment  | 2014 MAR 13                             |
| 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                  | Strongly disagree <input type="radio"/> |
| 2. Nothing would be better than smoking a cigarette right now | Strongly disagree <input type="radio"/> |
| 3. If it were possible I would probably smoke now             | Strongly 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                        | Strongly disagree <input type="radio"/> |
| 6. I have an urge for a cigarette                             | Strongly disagree <input type="radio"/> |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Questionnaire on smoking urges (QSU)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:13**

**Generated On: 20 Jul 2016 16:57:04**

---

7. A cigarette would taste good now Strongly disagree ☐

---

8. I would do almost anything for a cigarette now Strongly disagree ☐

---

9. Smoking would make me less depressed Strongly disagree ☐

---

10. I am going to smoke as soon as possible Strongly disagree ☐

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (CEMA, HPMa, HBMA)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:15**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:15**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112450002138    |
| Analyte                   | HPMA              |
| Sample type               | URINE             |
| Result                    | 398               |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 5                 |
| Celerion Study Number     | AA99128-03        |
| Date of Collection        | 2014-MAR-13       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 5                 |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (CEMA, HPMa, HBMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:15**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

6

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:15**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112450002138    |
| Analyte                   | CEMA              |
| Sample type               | URINE             |
| Result                    | 13.7              |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 5                 |
| Celerion Study Number     | AA99128-03        |
| Date of Collection        | 2014-MAR-13       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 5                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:15**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

6

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:15**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112450002138    |
| Analyte                   | HBMA              |
| Sample type               | URINE             |
| Result                    | 332               |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 5                 |
| Celerion Study Number     | AA99128-03        |
| Date of Collection        | 2014-MAR-13       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 5                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:15**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

6

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (NNN, NNAL)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:14**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (NNN, NNAL) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:14**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112460002549    |
| Analyte                   | NNAL              |
| Sample type               | URINE             |
| Result                    | 24.2              |
| Result Unit               | PG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 5                 |
| Celerion Study Number     | AA99128-04        |
| Date of Collection        | 2014-MAR-13       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 5                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (NNN, NNAL) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:14**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

6

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (NNN, NNAL) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:14**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112460002549    |
| Analyte                   | NNN               |
| Sample type               | URINE             |
| Result                    | 0.305             |
| Result Unit               | PG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 5                 |
| Celerion Study Number     | AA99128-04        |
| Date of Collection        | 2014-MAR-13       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 5                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (NNN, NNAL) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:14**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

6

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (HEMA)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:14**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (HEMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:14**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112470001273    |
| Analyte                   | HEMA              |
| Sample type               | URINE             |
| Result                    | 1.19              |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 5                 |
| Celerion Study Number     | AA99128-05        |
| Date of Collection        | 2014-MAR-13       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 5                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (HEMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:14**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

6

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:16**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:16**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112480000668    |
| Analyte                   | COT               |
| Sample type               | URINE             |
| Result                    | 1230              |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 5                 |
| Celerion Study Number     | AA99128-06        |
| Date of Collection        | 2014-MAR-13       |
| Timepoint-minutes         |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:16**

**Generated On: 20 Jul 2016 16:57:04**

---

|                 |   |
|-----------------|---|
| Urine Start Day | 5 |
|-----------------|---|

---

|               |   |
|---------------|---|
| Urine End Day | 6 |
|---------------|---|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:16**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112480000668    |
| Analyte                   | COT-GLUC          |
| Sample type               | URINE             |
| Result                    | 2370              |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 5                 |
| Celerion Study Number     | AA99128-06        |
| Date of Collection        | 2014-MAR-13       |
| Timepoint-minutes         |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:16**

**Generated On: 20 Jul 2016 16:57:04**

---

|                 |   |
|-----------------|---|
| Urine Start Day | 5 |
|-----------------|---|

---

|               |   |
|---------------|---|
| Urine End Day | 6 |
|---------------|---|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:16**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112480000668    |
| Analyte                   | NIC               |
| Sample type               | URINE             |
| Result                    | 585               |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 5                 |
| Celerion Study Number     | AA99128-06        |
| Date of Collection        | 2014-MAR-13       |
| Timepoint-minutes         |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:16**

**Generated On: 20 Jul 2016 16:57:04**

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|                 |   |
|-----------------|---|
| Urine Start Day | 5 |
|-----------------|---|

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|               |   |
|---------------|---|
| Urine End Day | 6 |
|---------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:16**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112480000668    |
| Analyte                   | NIC-GLUC          |
| Sample type               | URINE             |
| Result                    | 400               |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 5                 |
| Celerion Study Number     | AA99128-06        |
| Date of Collection        | 2014-MAR-13       |
| Timepoint-minutes         |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:16**

**Generated On: 20 Jul 2016 16:57:04**

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|                 |   |
|-----------------|---|
| Urine Start Day | 5 |
|-----------------|---|

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|               |   |
|---------------|---|
| Urine End Day | 6 |
|---------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(5)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:16**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112480000668    |
| Analyte                   | THCOT             |
| Sample type               | URINE             |
| Result                    | 2410              |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 5                 |
| Celerion Study Number     | AA99128-06        |
| Date of Collection        | 2014-MAR-13       |
| Timepoint-minutes         |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(5)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:16**

**Generated On: 20 Jul 2016 16:57:04**

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|                 |   |
|-----------------|---|
| Urine Start Day | 5 |
|-----------------|---|

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|               |   |
|---------------|---|
| Urine End Day | 6 |
|---------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(6)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:16**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112480000668    |
| Analyte                   | THCOT-GLUC        |
| Sample type               | URINE             |
| Result                    | 1040              |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 5                 |
| Celerion Study Number     | AA99128-06        |
| Date of Collection        | 2014-MAR-13       |
| Timepoint-minutes         |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)  
(6)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:16**

**Generated On: 20 Jul 2016 16:57:04**

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|                 |   |
|-----------------|---|
| Urine Start Day | 5 |
|-----------------|---|

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|               |   |
|---------------|---|
| Urine End Day | 6 |
|---------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (3-OH BaP)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:16**

**Generated On: 20 Jul 2016 16:57:04**

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Sample type

URINE

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (3-OH BaP) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:16**

**Generated On: 20 Jul 2016 16:57:04**

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|                |                |
|----------------|----------------|
| Sample Barcode | 05112490001273 |
|----------------|----------------|

---

|         |          |
|---------|----------|
| Analyte | 3-OH BAP |
|---------|----------|

---

|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

---

|        |            |
|--------|------------|
| Result | BLQ<(25.0) |
|--------|------------|

---

|             |       |
|-------------|-------|
| Result Unit | FG/ML |
|-------------|-------|

---

|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

---

|                |                   |
|----------------|-------------------|
| Sample comment | ANALYZED IN ERROR |
|----------------|-------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 5 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-07 |
|-----------------------|------------|

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|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-13 |
|--------------------|-------------|

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|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

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|                 |   |
|-----------------|---|
| Urine Start Day | 5 |
|-----------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (3-OH BaP) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:16**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

6

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Plasma (Caffeine, Paraxanthine)**

**Generated On: 20 Jul 2016 16:57:04**

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Sample type

PLASMA

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Plasma (Caffeine, Paraxanthine) (1)**

**Generated On: 20 Jul 2016 16:57:04**

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|                |                |
|----------------|----------------|
| Sample Barcode | 05112500000347 |
|----------------|----------------|

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|         |          |
|---------|----------|
| Analyte | CAFFEINE |
|---------|----------|

---

|             |        |
|-------------|--------|
| Sample type | PLASMA |
|-------------|--------|

---

|        |      |
|--------|------|
| Result | 1490 |
|--------|------|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

---

|                |                   |
|----------------|-------------------|
| Sample comment | ANALYZED IN ERROR |
|----------------|-------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 6 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 5 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-08 |
|-----------------------|------------|

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|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-13 |
|--------------------|-------------|

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|                   |   |
|-------------------|---|
| Timepoint-minutes | 0 |
|-------------------|---|

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|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Plasma (Caffeine, Paraxanthine) (1)**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

5

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Plasma (Caffeine, Paraxanthine) (2)**

**Generated On: 20 Jul 2016 16:57:04**

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|                |                |
|----------------|----------------|
| Sample Barcode | 05112500000347 |
|----------------|----------------|

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|         |              |
|---------|--------------|
| Analyte | PARAXANTHINE |
|---------|--------------|

---

|             |        |
|-------------|--------|
| Sample type | PLASMA |
|-------------|--------|

---

|        |      |
|--------|------|
| Result | 1320 |
|--------|------|

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|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

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|                |                   |
|----------------|-------------------|
| Sample comment | ANALYZED IN ERROR |
|----------------|-------------------|

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|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 6 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 5 |
|--------------|---|

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|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-08 |
|-----------------------|------------|

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|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-13 |
|--------------------|-------------|

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|                   |   |
|-------------------|---|
| Timepoint-minutes | 0 |
|-------------------|---|

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|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Plasma (Caffeine, Paraxanthine) (2)**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

5

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:16**

**Generated On: 20 Jul 2016 16:57:04**

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Sample type

URINE

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:16**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112510001295    |
| Analyte                   | 1-NA              |
| Sample type               | URINE             |
| Result                    | 4.03              |
| Result Unit               | PG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 5                 |
| Celerion Study Number     | AA99128-09        |
| Date of Collection        | 2014-MAR-13       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 5                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:16**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

6

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:16**

**Generated On: 20 Jul 2016 16:57:04**

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|                |                |
|----------------|----------------|
| Sample Barcode | 05112510001295 |
|----------------|----------------|

---

|         |      |
|---------|------|
| Analyte | 2-NA |
|---------|------|

---

|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

---

|        |            |
|--------|------------|
| Result | BLQ<(2.50) |
|--------|------------|

---

|             |       |
|-------------|-------|
| Result Unit | PG/ML |
|-------------|-------|

---

|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

---

|                |                   |
|----------------|-------------------|
| Sample comment | ANALYZED IN ERROR |
|----------------|-------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

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|              |   |
|--------------|---|
| Day of Visit | 5 |
|--------------|---|

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|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-09 |
|-----------------------|------------|

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|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-13 |
|--------------------|-------------|

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|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

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|                 |   |
|-----------------|---|
| Urine Start Day | 5 |
|-----------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:16**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

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6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:16**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112510001295    |
| Analyte                   | 4-ABP             |
| Sample type               | URINE             |
| Result                    | BLQ<(1.50)        |
| Result Unit               | PG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 5                 |
| Celerion Study Number     | AA99128-09        |
| Date of Collection        | 2014-MAR-13       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 5                 |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:16**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

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6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:16**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112510001295    |
| Analyte                   | O-TOL             |
| Sample type               | URINE             |
| Result                    | BLQ<(50.0)        |
| Result Unit               | PG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 5                 |
| Celerion Study Number     | AA99128-09        |
| Date of Collection        | 2014-MAR-13       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 5                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:16**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

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6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (11-dTXb2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:14**

**Generated On: 20 Jul 2016 16:57:04**

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Sample type

URINE

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (11-dTXb2) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:14**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112530000403    |
| Analyte                   | 11-DTXB2          |
| Sample type               | URINE             |
| Result                    | 369               |
| Result Unit               | PG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 5                 |
| Celerion Study Number     | AA99128-11        |
| Date of Collection        | 2014-MAR-13       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 5                 |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (11-dTXb2) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:14**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

6

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (iPF2a-III)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:14**

**Generated On: 20 Jul 2016 16:57:04**

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Sample type

URINE

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (iPF2a-III) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:14**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112540000403    |
| Analyte                   | IPF2A-III         |
| Sample type               | URINE             |
| Result                    | 163               |
| Result Unit               | PG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 5                 |
| Celerion Study Number     | AA99128-12        |
| Date of Collection        | 2014-MAR-13       |
| Timepoint-minutes         |                   |
| Urine Start Day           | 5                 |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (iPF2a-III) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:14**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

6

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (Ames)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:16**

**Generated On: 20 Jul 2016 16:57:04**

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Sample type

URINE

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (Ames) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:16**

**Generated On: 20 Jul 2016 16:57:04**

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|                |                |
|----------------|----------------|
| Sample Barcode | 05113320000128 |
|----------------|----------------|

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|         |      |
|---------|------|
| Analyte | AMES |
|---------|------|

---

|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

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|             |        |
|-------------|--------|
| Result Unit | REV/ML |
|-------------|--------|

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|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

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|                |                                    |
|----------------|------------------------------------|
| Sample comment | ANALYSIS NOT PERFORMED<br>IN ERROR |
|----------------|------------------------------------|

---

|                  |       |
|------------------|-------|
| Detection method | COUNT |
|------------------|-------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 5 |
|--------------|---|

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|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-15 |
|-----------------------|------------|

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|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-13 |
|--------------------|-------------|

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|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (Ames) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:16**

**Generated On: 20 Jul 2016 16:57:04**

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|                 |   |
|-----------------|---|
| Urine Start Day | 5 |
|-----------------|---|

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|               |   |
|---------------|---|
| Urine End Day | 6 |
|---------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (1-OHP)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:16**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

URINE

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (1-OHP) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:16**

**Generated On: 20 Jul 2016 16:57:04**

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|                |                |
|----------------|----------------|
| Sample Barcode | 05115190001570 |
|----------------|----------------|

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|         |       |
|---------|-------|
| Analyte | 1-OHP |
|---------|-------|

---

|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

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|        |   |
|--------|---|
| Result | . |
|--------|---|

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|             |       |
|-------------|-------|
| Result Unit | PG/ML |
|-------------|-------|

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|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | NOT ANALYZED IN ERROR |
|----------------|-----------------------|

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|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

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|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

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|              |   |
|--------------|---|
| Day of Visit | 5 |
|--------------|---|

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|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99598-03 |
|-----------------------|------------|

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|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-13 |
|--------------------|-------------|

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|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

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|                 |   |
|-----------------|---|
| Urine Start Day | 5 |
|-----------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (1-OHP) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:16**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

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6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (SPMA, SBMA)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:15**

**Generated On: 20 Jul 2016 16:57:04**

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Sample type

URINE

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (SPMA, SBMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:15**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                       |
|---------------------------|-----------------------|
| Sample Barcode            | 05115170001548        |
| Analyte                   | SBMA                  |
| Sample type               | URINE                 |
| Result                    | .                     |
| Result Unit               | NG/ML                 |
| Lab Status                | OK                    |
| Sample comment            | NOT ANALYZED IN ERROR |
| Detection method          | LC-MS/MS              |
| Planned time point (Hour) | 0                     |
| Day of Visit              | 5                     |
| Celerion Study Number     | AA99598-01            |
| Date of Collection        | 2014-MAR-13           |
| Timepoint-minutes         |                       |
| Urine Start Day           | 5                     |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (SPMA, SBMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:15**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

6

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (SPMA, SBMA) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:15**

**Generated On: 20 Jul 2016 16:57:04**

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|                |                |
|----------------|----------------|
| Sample Barcode | 05115170001548 |
|----------------|----------------|

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|         |      |
|---------|------|
| Analyte | SPMA |
|---------|------|

---

|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

---

|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | NOT ANALYZED IN ERROR |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 5 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99598-01 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-13 |
|--------------------|-------------|

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|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

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|                 |   |
|-----------------|---|
| Urine Start Day | 5 |
|-----------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (SPMA, SBMA) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:15**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

6

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (MHBMA)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:15**

**Generated On: 20 Jul 2016 16:57:04**

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Sample type

URINE

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (MHBMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:15**

**Generated On: 20 Jul 2016 16:57:04**

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|                |                |
|----------------|----------------|
| Sample Barcode | 05115180001570 |
|----------------|----------------|

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|         |       |
|---------|-------|
| Analyte | MHBMA |
|---------|-------|

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|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

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|        |   |
|--------|---|
| Result | . |
|--------|---|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

---

|                |                       |
|----------------|-----------------------|
| Sample comment | NOT ANALYZED IN ERROR |
|----------------|-----------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 5 |
|--------------|---|

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|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99598-02 |
|-----------------------|------------|

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|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-13 |
|--------------------|-------------|

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|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

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|                 |   |
|-----------------|---|
| Urine Start Day | 5 |
|-----------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (MHBMA) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:15**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

6

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (Creatinine)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:16**

**Generated On: 20 Jul 2016 16:57:04**

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Sample type

URINE

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (Creatinine) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:16**

**Generated On: 20 Jul 2016 16:57:04**

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|                |                |
|----------------|----------------|
| Sample Barcode | 05115160001273 |
|----------------|----------------|

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|         |            |
|---------|------------|
| Analyte | CREATININE |
|---------|------------|

---

|             |       |
|-------------|-------|
| Sample type | URINE |
|-------------|-------|

---

|        |     |
|--------|-----|
| Result | 127 |
|--------|-----|

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

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|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

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|                |                       |
|----------------|-----------------------|
| Sample comment | ANALYSIS NOT REQUIRED |
|----------------|-----------------------|

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|                  |                    |
|------------------|--------------------|
| Detection method | SPECTROPHOTOMETRIC |
|------------------|--------------------|

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|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

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|              |   |
|--------------|---|
| Day of Visit | 5 |
|--------------|---|

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|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-14 |
|-----------------------|------------|

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|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-13 |
|--------------------|-------------|

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|                   |  |
|-------------------|--|
| Timepoint-minutes |  |
|-------------------|--|

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|                 |   |
|-----------------|---|
| Urine Start Day | 5 |
|-----------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Urine (Creatinine) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:16**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

6

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:15**

**Generated On: 20 Jul 2016 16:57:04**

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Sample type

PLASMA

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:15**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112430001621    |
| Analyte                   | COT               |
| Sample type               | PLASMA            |
| Result                    | 244               |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 5                 |
| Celerion Study Number     | AA99128-01        |
| Date of Collection        | 2014-MAR-13       |
| Timepoint-minutes         | -15               |
| Urine Start Day           |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:15**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

5

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:15**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112430001621    |
| Analyte                   | NIC               |
| Sample type               | PLASMA            |
| Result                    | 3.85              |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 0                 |
| Day of Visit              | 5                 |
| Celerion Study Number     | AA99128-01        |
| Date of Collection        | 2014-MAR-13       |
| Timepoint-minutes         | -15               |
| Urine Start Day           |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:15**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

5

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:15**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112430001622    |
| Analyte                   | COT               |
| Sample type               | PLASMA            |
| Result                    | 243               |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 2                 |
| Day of Visit              | 5                 |
| Celerion Study Number     | AA99128-01        |
| Date of Collection        | 2014-MAR-13       |
| Timepoint-minutes         | 0                 |
| Urine Start Day           |                   |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:15**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

5

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:15**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112430001622    |
| Analyte                   | NIC               |
| Sample type               | PLASMA            |
| Result                    | 10.7              |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 2                 |
| Day of Visit              | 5                 |
| Celerion Study Number     | AA99128-01        |
| Date of Collection        | 2014-MAR-13       |
| Timepoint-minutes         | 0                 |
| Urine Start Day           |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:15**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

5

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (5)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:15**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112430001623    |
| Analyte                   | COT               |
| Sample type               | PLASMA            |
| Result                    | 225               |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 4                 |
| Day of Visit              | 5                 |
| Celerion Study Number     | AA99128-01        |
| Date of Collection        | 2014-MAR-13       |
| Timepoint-minutes         | 0                 |
| Urine Start Day           |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (5)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:15**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

5

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (6)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:15**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112430001623    |
| Analyte                   | NIC               |
| Sample type               | PLASMA            |
| Result                    | 6.36              |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 4                 |
| Day of Visit              | 5                 |
| Celerion Study Number     | AA99128-01        |
| Date of Collection        | 2014-MAR-13       |
| Timepoint-minutes         | 0                 |
| Urine Start Day           |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (6)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:15**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

5

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (7)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:15**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112430001624    |
| Analyte                   | COT               |
| Sample type               | PLASMA            |
| Result                    | 225               |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 6                 |
| Day of Visit              | 5                 |
| Celerion Study Number     | AA99128-01        |
| Date of Collection        | 2014-MAR-13       |
| Timepoint-minutes         | 0                 |
| Urine Start Day           |                   |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (7)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:15**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

5

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (8)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:15**

**Generated On: 20 Jul 2016 16:57:04**

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|                |                |
|----------------|----------------|
| Sample Barcode | 05112430001624 |
|----------------|----------------|

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|         |     |
|---------|-----|
| Analyte | NIC |
|---------|-----|

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|             |        |
|-------------|--------|
| Sample type | PLASMA |
|-------------|--------|

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|        |      |
|--------|------|
| Result | 11.3 |
|--------|------|

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|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

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|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

---

|                |                   |
|----------------|-------------------|
| Sample comment | ANALYZED IN ERROR |
|----------------|-------------------|

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|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

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|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 6 |
|---------------------------|---|

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|              |   |
|--------------|---|
| Day of Visit | 5 |
|--------------|---|

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|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-01 |
|-----------------------|------------|

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|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-13 |
|--------------------|-------------|

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|                   |   |
|-------------------|---|
| Timepoint-minutes | 0 |
|-------------------|---|

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|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (8)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:15**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

5

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (9)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:15**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112430001625    |
| Analyte                   | COT               |
| Sample type               | PLASMA            |
| Result                    | 227               |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 8                 |
| Day of Visit              | 5                 |
| Celerion Study Number     | AA99128-01        |
| Date of Collection        | 2014-MAR-13       |
| Timepoint-minutes         | 0                 |
| Urine Start Day           |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (9)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:15**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

5

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (10)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:15**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112430001625    |
| Analyte                   | NIC               |
| Sample type               | PLASMA            |
| Result                    | 11.7              |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 8                 |
| Day of Visit              | 5                 |
| Celerion Study Number     | AA99128-01        |
| Date of Collection        | 2014-MAR-13       |
| Timepoint-minutes         | 0                 |
| Urine Start Day           |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (10)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:15**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

5

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (11)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:15**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112430001626    |
| Analyte                   | COT               |
| Sample type               | PLASMA            |
| Result                    | 214               |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 10                |
| Day of Visit              | 5                 |
| Celerion Study Number     | AA99128-01        |
| Date of Collection        | 2014-MAR-13       |
| Timepoint-minutes         | 0                 |
| Urine Start Day           |                   |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (11)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:15**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

5

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (12)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:15**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112430001626    |
| Analyte                   | NIC               |
| Sample type               | PLASMA            |
| Result                    | 12.5              |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 10                |
| Day of Visit              | 5                 |
| Celerion Study Number     | AA99128-01        |
| Date of Collection        | 2014-MAR-13       |
| Timepoint-minutes         | 0                 |
| Urine Start Day           |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (12)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:15**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

5

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (13)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:15**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112430001627    |
| Analyte                   | COT               |
| Sample type               | PLASMA            |
| Result                    | 233               |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 12                |
| Day of Visit              | 5                 |
| Celerion Study Number     | AA99128-01        |
| Date of Collection        | 2014-MAR-13       |
| Timepoint-minutes         | 0                 |
| Urine Start Day           |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (13)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:15**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

5

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (14)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:15**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112430001627    |
| Analyte                   | NIC               |
| Sample type               | PLASMA            |
| Result                    | 12.2              |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 12                |
| Day of Visit              | 5                 |
| Celerion Study Number     | AA99128-01        |
| Date of Collection        | 2014-MAR-13       |
| Timepoint-minutes         | 0                 |
| Urine Start Day           |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (14)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:15**

**Generated On: 20 Jul 2016 16:57:04**

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Urine End Day

5

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (15)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:15**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112430001628    |
| Analyte                   | COT               |
| Sample type               | PLASMA            |
| Result                    | 223               |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 14                |
| Day of Visit              | 5                 |
| Celerion Study Number     | AA99128-01        |
| Date of Collection        | 2014-MAR-13       |
| Timepoint-minutes         | 0                 |
| Urine Start Day           |                   |



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (15)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:15**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

5

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (16)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:15**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112430001628    |
| Analyte                   | NIC               |
| Sample type               | PLASMA            |
| Result                    | 12.8              |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 14                |
| Day of Visit              | 5                 |
| Celerion Study Number     | AA99128-01        |
| Date of Collection        | 2014-MAR-13       |
| Timepoint-minutes         | 0                 |
| Urine Start Day           |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (16)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:15**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

5

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (17)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:15**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112430001629    |
| Analyte                   | COT               |
| Sample type               | PLASMA            |
| Result                    | 218               |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 16                |
| Day of Visit              | 5                 |
| Celerion Study Number     | AA99128-01        |
| Date of Collection        | 2014-MAR-13       |
| Timepoint-minutes         | 0                 |
| Urine Start Day           |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (17)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:15**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

5

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (18)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:15**

**Generated On: 20 Jul 2016 16:57:04**

|                           |                   |
|---------------------------|-------------------|
| Sample Barcode            | 05112430001629    |
| Analyte                   | NIC               |
| Sample type               | PLASMA            |
| Result                    | 16.4              |
| Result Unit               | NG/ML             |
| Lab Status                | OK                |
| Sample comment            | ANALYZED IN ERROR |
| Detection method          | LC-MS/MS          |
| Planned time point (Hour) | 16                |
| Day of Visit              | 5                 |
| Celerion Study Number     | AA99128-01        |
| Date of Collection        | 2014-MAR-13       |
| Timepoint-minutes         | 0                 |
| Urine Start Day           |                   |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 5**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (18)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:15**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

5

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 6**

**Form: Date of Visit**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:16**

**Generated On: 20 Jul 2016 16:57:04**

---

Date of Visit

14 MAR 2014  
DD/MMM/YYYY

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 6**

**Form: Plasma Nicotine Samples <Day 6> (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:16**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

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

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 14 MAR 2014 |
|---------------------|-------------|

---

|                |   |
|----------------|---|
| Scheduled Time | T0 + 20H <input checked="" type="radio"/> |
|----------------|---|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 02:38 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 6**

**Form: Plasma Nicotine Samples <Day 6> (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:16**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

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

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 14 MAR 2014 |
|---------------------|-------------|

---

|                |   |
|----------------|---|
| Scheduled Time | T0 + 24H <input checked="" type="radio"/> |
|----------------|---|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 06:41 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 6**

**Form: Plasma Cotinine Samples <Day 6> (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:16**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

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

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 14 MAR 2014 |
|---------------------|-------------|

---

|                |   |
|----------------|---|
| Scheduled Time | T0 + 20H <input checked="" type="radio"/> |
|----------------|---|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 02:38 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 6**

**Form: Plasma Cotinine Samples <Day 6> (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:16**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

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

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 14 MAR 2014 |
|---------------------|-------------|

---

|                |   |
|----------------|---|
| Scheduled Time | T0 + 24H <input checked="" type="radio"/> |
|----------------|---|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 06:41 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 6**

**Form: CoHb Blood Sample <prior to gas transfer and product>**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:16**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

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

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 14 MAR 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 | 06:41 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 6**

**Form: Oxysterols**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:16**

**Generated On: 20 Jul 2016 16:57:04**

---

|          |       |
|----------|-------|
| 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 | 14 MAR 2014 |
|---------------------|-------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 06:41 |
|--------------------------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Day 6**

**Form: CYP2A6 activity Sample**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:16**

**Generated On: 20 Jul 2016 16:57:04**

---

|          |       |
|----------|-------|
| 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

---

14 MAR 2014

06:41

trans-3'-hydroxyc  
otinine

---

14 MAR 2014

06:41

cotinine

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 6**

**Form: Risk Marker: sICAM-1**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:16**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

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

---

|                     |             |
|---------------------|-------------|
| Date<br>DD/MMM/YYYY | 14 MAR 2014 |
|---------------------|-------------|

---

|                                |       |
|--------------------------------|-------|
| Time<br>hour:min 24-hour clock | 06:41 |
|--------------------------------|-------|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 6**

**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:17**

**Generated On: 20 Jul 2016 16:57:04**

---

Date of Birth

(b) (6)

---

Date of assessment  
DD/MMM/YYYY

2014 MAR 14  
DD/MMM/YYYY

---

Time of assessment

05:56  
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?

Mild ☐

4. Desire or craving to smoke

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 6**

**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:17**

**Generated On: 20 Jul 2016 16:57:04**

---

How have you been feeling over the past 24 hours? None ☐

5. Difficulty concentrating

---

How have you been feeling over the past 24 hours? None ☐

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? None ☐

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: 1194**

**Folder: Day 6**

**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:17**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Day 6**

**Form: Cough Assessment**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:17**

**Generated On: 20 Jul 2016 16:57:04**

---

Date of Birth

(b) (6)

---

Date of assessment  
DD/MMM/YYYY

2014 MAR 14  
DD/MMM/YYYY

---

Time of assessment

05:55  
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: 1194**

**Folder: Day 6**

**Form: Bio-banking (Transcriptomics)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:17**

**Generated On: 20 Jul 2016 16:57:04**

---

Was a Bio-banking sample for transcriptomics taken?

Yes ☒

---

Time of Sample Collection

06:41  
hour:min 24-hour clock

---

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

Yes ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 6**

**Form: Bio-banking (Biomarkers of exposure and risk markers)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:16**

**Generated On: 20 Jul 2016 16:57:04**

---

Was a Bio-banking sample for biomarkers of exposure  
and risk markers taken?

Yes ☒

---

Time of Sample Collection

06:41  
hour:min 24-hour clock

---

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

Yes ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 6**

**Form: Bio-banking (nasal epithelial collection/buccal collection)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:17**

**Generated On: 20 Jul 2016 16:57:04**

---

|   |                                      |
|---|--------------------------------------|
| Was a Bio-banking sample for nasal epithelial collection/buccal collection taken? | Yes <input checked="" type="radio"/> |
|---|--------------------------------------|

---

|                           |                        |
|---------------------------|------------------------|
| Time of Buccal Collection | 09:54                  |
|                           | hour:min 24-hour clock |

---

|                                     |                        |
|-------------------------------------|------------------------|
| Time of Nasal Epithelial Collection | 09:51                  |
|                                     | hour:min 24-hour clock |

---

|   |                                      |
|---|--------------------------------------|
| Was the subject fasting for at least 30 minutes at time of sample collection? | Yes <input checked="" type="radio"/> |
|---|--------------------------------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 6**

**Form: Oxysterol results (1)**

**Generated On: 20 Jul 2016 16:57:04**

---

|                         |            |
|-------------------------|------------|
| Sample Accession number | 3281672415 |
|-------------------------|------------|

---

|         |                              |
|---------|------------------------------|
| Analyte | 22(R)-HYDROXYCHOLESTERO<br>L |
|---------|------------------------------|

---

|              |         |
|--------------|---------|
| Analyte code | 22RHCRL |
|--------------|---------|

---

|        |  |
|--------|--|
| Result |  |
|--------|--|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|         |  |
|---------|--|
| Comment | NOT ANALYSED, INCOMPLETE<br>SAMPLE SET |
|---------|--|

---

|                               |      |
|-------------------------------|------|
| Lower limit of quantification | 9.46 |
|-------------------------------|------|

---

|                                   |  |
|-----------------------------------|--|
| Date of Collection<br>DD MMM YYYY |  |
|-----------------------------------|--|

---

|  |  |
|--|--|
| Collection time<br>hh:mm 24 hour clock |  |
|--|--|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 6**

**Form: Oxysterol results (2)**

**Generated On: 20 Jul 2016 16:57:04**

---

|                         |            |
|-------------------------|------------|
| Sample Accession number | 3281672415 |
|-------------------------|------------|

---

|         |                              |
|---------|------------------------------|
| Analyte | 24(R)-HYDROXYCHOLESTERO<br>L |
|---------|------------------------------|

---

|              |         |
|--------------|---------|
| Analyte code | 24RHCRL |
|--------------|---------|

---

|        |  |
|--------|--|
| Result |  |
|--------|--|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|         |  |
|---------|--|
| Comment | NOT ANALYSED, INCOMPLETE<br>SAMPLE SET |
|---------|--|

---

|                               |      |
|-------------------------------|------|
| Lower limit of quantification | 6.56 |
|-------------------------------|------|

---

|                                   |  |
|-----------------------------------|--|
| Date of Collection<br>DD MMM YYYY |  |
|-----------------------------------|--|

---

|  |  |
|--|--|
| Collection time<br>hh:mm 24 hour clock |  |
|--|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 6**

**Form: Oxysterol results (3)**

**Generated On: 20 Jul 2016 16:57:04**

---

|                         |            |
|-------------------------|------------|
| Sample Accession number | 3281672415 |
|-------------------------|------------|

---

|         |                       |
|---------|-----------------------|
| Analyte | 25-HYDROXYCHOLESTEROL |
|---------|-----------------------|

---

|              |        |
|--------------|--------|
| Analyte code | 25HCRL |
|--------------|--------|

---

|        |  |
|--------|--|
| Result |  |
|--------|--|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|         |  |
|---------|--|
| Comment | NOT ANALYSED, INCOMPLETE<br>SAMPLE SET |
|---------|--|

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|                               |      |
|-------------------------------|------|
| Lower limit of quantification | 4.70 |
|-------------------------------|------|

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|                                   |  |
|-----------------------------------|--|
| Date of Collection<br>DD MMM YYYY |  |
|-----------------------------------|--|

---

|  |  |
|--|--|
| Collection time<br>hh:mm 24 hour clock |  |
|--|--|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 6**

**Form: Oxysterol results (4)**

**Generated On: 20 Jul 2016 16:57:04**

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|                         |            |
|-------------------------|------------|
| Sample Accession number | 3281672415 |
|-------------------------|------------|

---

|         |                       |
|---------|-----------------------|
| Analyte | 27-HYDROXYCHOLESTEROL |
|---------|-----------------------|

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|              |        |
|--------------|--------|
| Analyte code | 27HCRL |
|--------------|--------|

---

|        |  |
|--------|--|
| Result |  |
|--------|--|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|         |  |
|---------|--|
| Comment | NOT ANALYSED, INCOMPLETE<br>SAMPLE SET |
|---------|--|

---

|                               |       |
|-------------------------------|-------|
| Lower limit of quantification | 11.60 |
|-------------------------------|-------|

---

|                                   |  |
|-----------------------------------|--|
| Date of Collection<br>DD MMM YYYY |  |
|-----------------------------------|--|

---

|  |  |
|--|--|
| Collection time<br>hh:mm 24 hour clock |  |
|--|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 6**

**Form: Oxysterol results (5)**

**Generated On: 20 Jul 2016 16:57:04**

---

|                         |            |
|-------------------------|------------|
| Sample Accession number | 3281672415 |
|-------------------------|------------|

---

|         |                       |
|---------|-----------------------|
| Analyte | 4B-HYDROXYCHOLESTEROL |
|---------|-----------------------|

---

|              |        |
|--------------|--------|
| Analyte code | 4BHCRL |
|--------------|--------|

---

|        |  |
|--------|--|
| Result |  |
|--------|--|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|         |  |
|---------|--|
| Comment | NOT ANALYSED, INCOMPLETE<br>SAMPLE SET |
|---------|--|

---

|                               |       |
|-------------------------------|-------|
| Lower limit of quantification | 10.66 |
|-------------------------------|-------|

---

|                                   |  |
|-----------------------------------|--|
| Date of Collection<br>DD MMM YYYY |  |
|-----------------------------------|--|

---

|  |  |
|--|--|
| Collection time<br>hh:mm 24 hour clock |  |
|--|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 6**

**Form: Oxysterol results (6)**

**Generated On: 20 Jul 2016 16:57:04**

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|                         |            |
|-------------------------|------------|
| Sample Accession number | 3281672415 |
|-------------------------|------------|

---

|         |                        |
|---------|------------------------|
| Analyte | 5A,6A-EPOXYCHOLESTANOL |
|---------|------------------------|

---

|              |          |
|--------------|----------|
| Analyte code | 5A6AECNL |
|--------------|----------|

---

|        |  |
|--------|--|
| Result |  |
|--------|--|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|         |  |
|---------|--|
| Comment | NOT ANALYSED, INCOMPLETE<br>SAMPLE SET |
|---------|--|

---

|                               |       |
|-------------------------------|-------|
| Lower limit of quantification | 12.46 |
|-------------------------------|-------|

---

|                                   |  |
|-----------------------------------|--|
| Date of Collection<br>DD MMM YYYY |  |
|-----------------------------------|--|

---

|  |  |
|--|--|
| Collection time<br>hh:mm 24 hour clock |  |
|--|--|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 6**

**Form: Oxysterol results (7)**

**Generated On: 20 Jul 2016 16:57:04**

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|                         |            |
|-------------------------|------------|
| Sample Accession number | 3281672415 |
|-------------------------|------------|

---

|         |                        |
|---------|------------------------|
| Analyte | 5B,6B-EPOXYCHOLESTANOL |
|---------|------------------------|

---

|              |          |
|--------------|----------|
| Analyte code | 5B6BECNL |
|--------------|----------|

---

|        |  |
|--------|--|
| Result |  |
|--------|--|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|         |  |
|---------|--|
| Comment | NOT ANALYSED, INCOMPLETE<br>SAMPLE SET |
|---------|--|

---

|                               |       |
|-------------------------------|-------|
| Lower limit of quantification | 26.83 |
|-------------------------------|-------|

---

|                                   |  |
|-----------------------------------|--|
| Date of Collection<br>DD MMM YYYY |  |
|-----------------------------------|--|

---

|  |  |
|--|--|
| Collection time<br>hh:mm 24 hour clock |  |
|--|--|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 6**

**Form: Oxysterol results (8)**

**Generated On: 20 Jul 2016 16:57:04**

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|                         |            |
|-------------------------|------------|
| Sample Accession number | 3281672415 |
|-------------------------|------------|

---

|         |                               |
|---------|-------------------------------|
| Analyte | 6A-HYDROXY-5A-CHOLESTAN<br>OL |
|---------|-------------------------------|

---

|              |          |
|--------------|----------|
| Analyte code | 6AH5ACNL |
|--------------|----------|

---

|        |  |
|--------|--|
| Result |  |
|--------|--|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|         |  |
|---------|--|
| Comment | NOT ANALYSED, INCOMPLETE<br>SAMPLE SET |
|---------|--|

---

|                               |       |
|-------------------------------|-------|
| Lower limit of quantification | 13.70 |
|-------------------------------|-------|

---

|                                   |  |
|-----------------------------------|--|
| Date of Collection<br>DD MMM YYYY |  |
|-----------------------------------|--|

---

|  |  |
|--|--|
| Collection time<br>hh:mm 24 hour clock |  |
|--|--|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 6**

**Form: Oxysterol results (9)**

**Generated On: 20 Jul 2016 16:57:04**

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|                         |            |
|-------------------------|------------|
| Sample Accession number | 3281672415 |
|-------------------------|------------|

---

|         |                   |
|---------|-------------------|
| Analyte | 7-KETOCHOLESTEROL |
|---------|-------------------|

---

|              |       |
|--------------|-------|
| Analyte code | 7KCRL |
|--------------|-------|

---

|        |  |
|--------|--|
| Result |  |
|--------|--|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|         |  |
|---------|--|
| Comment | NOT ANALYSED, INCOMPLETE<br>SAMPLE SET |
|---------|--|

---

|                               |       |
|-------------------------------|-------|
| Lower limit of quantification | 15.43 |
|-------------------------------|-------|

---

|                                   |  |
|-----------------------------------|--|
| Date of Collection<br>DD MMM YYYY |  |
|-----------------------------------|--|

---

|  |  |
|--|--|
| Collection time<br>hh:mm 24 hour clock |  |
|--|--|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 6**

**Form: Oxysterol results (10)**

**Generated On: 20 Jul 2016 16:57:04**

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|                         |            |
|-------------------------|------------|
| Sample Accession number | 3281672415 |
|-------------------------|------------|

---

|         |                       |
|---------|-----------------------|
| Analyte | 7A-HYDROXYCHOLESTEROL |
|---------|-----------------------|

---

|              |        |
|--------------|--------|
| Analyte code | 7AHCRL |
|--------------|--------|

---

|        |  |
|--------|--|
| Result |  |
|--------|--|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|         |  |
|---------|--|
| Comment | NOT ANALYSED, INCOMPLETE<br>SAMPLE SET |
|---------|--|

---

|                               |       |
|-------------------------------|-------|
| Lower limit of quantification | 13.46 |
|-------------------------------|-------|

---

|                                   |  |
|-----------------------------------|--|
| Date of Collection<br>DD MMM YYYY |  |
|-----------------------------------|--|

---

|  |  |
|--|--|
| Collection time<br>hh:mm 24 hour clock |  |
|--|--|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 6**

**Form: Oxysterol results (11)**

**Generated On: 20 Jul 2016 16:57:04**

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|                         |            |
|-------------------------|------------|
| Sample Accession number | 3281672415 |
|-------------------------|------------|

---

|         |                       |
|---------|-----------------------|
| Analyte | 7B-HYDROXYCHOLESTEROL |
|---------|-----------------------|

---

|              |        |
|--------------|--------|
| Analyte code | 7BHCRL |
|--------------|--------|

---

|        |  |
|--------|--|
| Result |  |
|--------|--|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|         |  |
|---------|--|
| Comment | NOT ANALYSED, INCOMPLETE<br>SAMPLE SET |
|---------|--|

---

|                               |       |
|-------------------------------|-------|
| Lower limit of quantification | 12.86 |
|-------------------------------|-------|

---

|                                   |  |
|-----------------------------------|--|
| Date of Collection<br>DD MMM YYYY |  |
|-----------------------------------|--|

---

|  |  |
|--|--|
| Collection time<br>hh:mm 24 hour clock |  |
|--|--|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 6**

**Form: Oxysterol results (12)**

**Generated On: 20 Jul 2016 16:57:04**

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|                         |            |
|-------------------------|------------|
| Sample Accession number | 3281672415 |
|-------------------------|------------|

---

|         |             |
|---------|-------------|
| Analyte | CHOLESTEROL |
|---------|-------------|

---

|              |      |
|--------------|------|
| Analyte code | CHOL |
|--------------|------|

---

|        |  |
|--------|--|
| Result |  |
|--------|--|

---

|             |       |
|-------------|-------|
| Result Unit | MG/ML |
|-------------|-------|

---

|         |  |
|---------|--|
| Comment | NOT ANALYSED, INCOMPLETE<br>SAMPLE SET |
|---------|--|

---

|                               |      |
|-------------------------------|------|
| Lower limit of quantification | 0.50 |
|-------------------------------|------|

---

|                                   |  |
|-----------------------------------|--|
| Date of Collection<br>DD MMM YYYY |  |
|-----------------------------------|--|

---

|  |  |
|--|--|
| Collection time<br>hh:mm 24 hour clock |  |
|--|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 6**

**Form: Lab\_BU\_COHB (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:17**

**Generated On: 20 Jul 2016 16:57:04**

|                               |                    |
|-------------------------------|--------------------|
| Sample Barcode                | 05115150001276     |
| Analyte                       | CARBOXYHEMOGLOBIN  |
| Sample type                   | BLOOD              |
| Result                        | 2.60               |
| Result Unit                   | %                  |
| Lab Status                    | OK                 |
| Sample comment                | .                  |
| 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-MAR-14        |
| Timepoint-minutes             |                    |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 6**

**Form: Lab\_BU\_COHB (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:17**

**Generated On: 20 Jul 2016 16:57:04**

---

Start Day (24 hour urine only) \_\_\_\_\_

---

End Day (24 hour Urine Only) \_\_\_\_\_

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 6**

**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:17**

**Generated On: 20 Jul 2016 16:57:04**

---

Date of Birth

(b) (6)

---

Date of assessment

2014 MAR 14

DD/MMM/YYYY

DD/MMM/YYYY

---

Time of assessment

07:04

hour:min 24-hour clock

---

Assessment Status

Abandoned

---

1. Was smoking satisfying?

Abandoned

---

2. Did cigarettes taste good?

Abandoned

---

3. Did you enjoy the sensation in your throat and chest?

Abandoned

---

4. Did smoking calm you down?

Abandoned

---

5. Did smoking make you feel more awake?

Abandoned

---

6. Did smoking make you feel less irritable?

Abandoned

---

7. Did smoking help you concentrate?

Abandoned

---

8. Did smoking reduce your hunger for food?

Abandoned

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 6**

**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:17**

**Generated On: 20 Jul 2016 16:57:04**

---

|                                |                                 |
|--------------------------------|---------------------------------|
| 9. Did smoking make you dizzy? | Abandoned <input type="radio"/> |
|--------------------------------|---------------------------------|

---

|                                    |                                 |
|------------------------------------|---------------------------------|
| 10. Did smoking make you nauseous? | Abandoned <input type="radio"/> |
|------------------------------------|---------------------------------|

---

|  |                                 |
|--|---------------------------------|
| 11. Did smoking immediately relieve your craving for a<br>cigarette? | Abandoned <input type="radio"/> |
|--|---------------------------------|

---

|                            |                                 |
|----------------------------|---------------------------------|
| 12. Did you enjoy smoking? | Abandoned <input type="radio"/> |
|----------------------------|---------------------------------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 6**

**Form: Risk Markers(CCLS) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:17**

**Generated On: 20 Jul 2016 16:57:04**

---

|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

---

|                      |      |
|----------------------|------|
| Subject ID or Number | 1194 |
|----------------------|------|

---

|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

---

|                       |                          |
|-----------------------|--------------------------|
| Subject Date of Birth | (b) <input type="text"/> |
|-----------------------|--------------------------|

---

|            |      |
|------------|------|
| Visit Name | DAY6 |
|------------|------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W816724 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 14 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:41 |
|------------------------|-------|

---

|                    |                      |
|--------------------|----------------------|
| Specimen Condition | <input type="text"/> |
|--------------------|----------------------|

---

|            |        |
|------------|--------|
| Battery ID | IM2293 |
|------------|--------|

---

|              |         |
|--------------|---------|
| Battery Name | SICAM-1 |
|--------------|---------|

---

|             |         |
|-------------|---------|
| Lab Test ID | IMT1768 |
|-------------|---------|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Day 6**

**Form: Risk Markers(CCLS) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:17**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | SICAM-1-RUO                           |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 242.9                                 |
| Reported Numeric Result           | 242.9                                 |
| 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: 1194**

**Folder: Day 6**

**Form: Risk Markers(CCLS) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:17**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Day 6**

**Form: Biomarker-Plasma (Nic, Cot, tHCot)**

**Generated On: 20 Jul 2016 16:57:04**

---

Sample type

PLASMA

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 6**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)**

**Generated On: 20 Jul 2016 16:57:04**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05112430001630 |
|----------------|----------------|

---

|         |     |
|---------|-----|
| Analyte | COT |
|---------|-----|

---

|             |        |
|-------------|--------|
| Sample type | PLASMA |
|-------------|--------|

---

|        |     |
|--------|-----|
| Result | 246 |
|--------|-----|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

---

|                |                   |
|----------------|-------------------|
| Sample comment | ANALYZED IN ERROR |
|----------------|-------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |    |
|---------------------------|----|
| Planned time point (Hour) | 20 |
|---------------------------|----|

---

|              |   |
|--------------|---|
| Day of Visit | 6 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-01 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-14 |
|--------------------|-------------|

---

|                   |   |
|-------------------|---|
| Timepoint-minutes | 0 |
|-------------------|---|

---

|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 6**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

5

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 6**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)**

**Generated On: 20 Jul 2016 16:57:04**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05112430001630 |
|----------------|----------------|

---

|         |     |
|---------|-----|
| Analyte | NIC |
|---------|-----|

---

|             |        |
|-------------|--------|
| Sample type | PLASMA |
|-------------|--------|

---

|        |      |
|--------|------|
| Result | 9.06 |
|--------|------|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

---

|                |                   |
|----------------|-------------------|
| Sample comment | ANALYZED IN ERROR |
|----------------|-------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |    |
|---------------------------|----|
| Planned time point (Hour) | 20 |
|---------------------------|----|

---

|              |   |
|--------------|---|
| Day of Visit | 6 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-01 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-14 |
|--------------------|-------------|

---

|                   |   |
|-------------------|---|
| Timepoint-minutes | 0 |
|-------------------|---|

---

|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 6**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

5

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 6**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)**

**Generated On: 20 Jul 2016 16:57:04**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05112430001631 |
|----------------|----------------|

---

|         |     |
|---------|-----|
| Analyte | COT |
|---------|-----|

---

|             |        |
|-------------|--------|
| Sample type | PLASMA |
|-------------|--------|

---

|        |     |
|--------|-----|
| Result | 218 |
|--------|-----|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

---

|                |                   |
|----------------|-------------------|
| Sample comment | ANALYZED IN ERROR |
|----------------|-------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |    |
|---------------------------|----|
| Planned time point (Hour) | 24 |
|---------------------------|----|

---

|              |   |
|--------------|---|
| Day of Visit | 6 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-01 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-14 |
|--------------------|-------------|

---

|                   |   |
|-------------------|---|
| Timepoint-minutes | 0 |
|-------------------|---|

---

|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 6**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)**

**Generated On: 20 Jul 2016 16:57:04**

---

|               |   |
|---------------|---|
| Urine End Day | 5 |
|---------------|---|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 6**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)**

**Generated On: 20 Jul 2016 16:57:04**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05112430001631 |
|----------------|----------------|

---

|         |     |
|---------|-----|
| Analyte | NIC |
|---------|-----|

---

|             |        |
|-------------|--------|
| Sample type | PLASMA |
|-------------|--------|

---

|        |      |
|--------|------|
| Result | 4.51 |
|--------|------|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

---

|                |                   |
|----------------|-------------------|
| Sample comment | ANALYZED IN ERROR |
|----------------|-------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |    |
|---------------------------|----|
| Planned time point (Hour) | 24 |
|---------------------------|----|

---

|              |   |
|--------------|---|
| Day of Visit | 6 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-01 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-14 |
|--------------------|-------------|

---

|                   |   |
|-------------------|---|
| Timepoint-minutes | 0 |
|-------------------|---|

---

|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 6**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

5

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 6**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (5)**

**Generated On: 20 Jul 2016 16:57:04**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05112520000347 |
|----------------|----------------|

---

|         |     |
|---------|-----|
| Analyte | COT |
|---------|-----|

---

|             |        |
|-------------|--------|
| Sample type | PLASMA |
|-------------|--------|

---

|        |     |
|--------|-----|
| Result | 226 |
|--------|-----|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

---

|                |                   |
|----------------|-------------------|
| Sample comment | ANALYZED IN ERROR |
|----------------|-------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 6 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-10 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-14 |
|--------------------|-------------|

---

|                   |   |
|-------------------|---|
| Timepoint-minutes | 0 |
|-------------------|---|

---

|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 6**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (5)**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

6

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 6**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (6)**

**Generated On: 20 Jul 2016 16:57:04**

---

|                |                |
|----------------|----------------|
| Sample Barcode | 05112520000347 |
|----------------|----------------|

---

|         |       |
|---------|-------|
| Analyte | THCOT |
|---------|-------|

---

|             |        |
|-------------|--------|
| Sample type | PLASMA |
|-------------|--------|

---

|        |      |
|--------|------|
| Result | 70.4 |
|--------|------|

---

|             |       |
|-------------|-------|
| Result Unit | NG/ML |
|-------------|-------|

---

|            |    |
|------------|----|
| Lab Status | OK |
|------------|----|

---

|                |                   |
|----------------|-------------------|
| Sample comment | ANALYZED IN ERROR |
|----------------|-------------------|

---

|                  |          |
|------------------|----------|
| Detection method | LC-MS/MS |
|------------------|----------|

---

|                           |   |
|---------------------------|---|
| Planned time point (Hour) | 0 |
|---------------------------|---|

---

|              |   |
|--------------|---|
| Day of Visit | 6 |
|--------------|---|

---

|                       |            |
|-----------------------|------------|
| Celerion Study Number | AA99128-10 |
|-----------------------|------------|

---

|                    |             |
|--------------------|-------------|
| Date of Collection | 2014-MAR-14 |
|--------------------|-------------|

---

|                   |   |
|-------------------|---|
| Timepoint-minutes | 0 |
|-------------------|---|

---

|                 |  |
|-----------------|--|
| Urine Start Day |  |
|-----------------|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Day 6**

**Form: Biomarker-Plasma (Nic, Cot, tHCot) (6)**

**Generated On: 20 Jul 2016 16:57:04**

---

Urine End Day

6

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Date of Discharge**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:20**

**Generated On: 20 Jul 2016 16:57:04**

---

|               |                            |
|---------------|----------------------------|
| Date of Visit | 14 MAR 2014<br>DD/MMM/YYYY |
|---------------|----------------------------|

---

|                |                                 |
|----------------|---------------------------------|
| Discharge Time | 11:40<br>hour:min 24-hour clock |
|----------------|---------------------------------|

---

|   |                                      |
|---|--------------------------------------|
| Is the subject continuing in the ambulatory period? | Yes <input checked="" type="radio"/> |
|---|--------------------------------------|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Vital Signs**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:20**

**Generated On: 20 Jul 2016 16:57:04**

---

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 08:53  
hour:min 24-hour clock

---

Pulse rate 61  
beats per minute

---

Respiratory rate 16  
breaths per minute

---

Blood Pressure (systolic) 132  
mmHg

---

Blood Pressure (diastolic) 82  
mmHg

---

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Discharge (Confinement)**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:35:20**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Discharge (Confinement)**

**Form: Physical Examination**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:18**

**Generated On: 20 Jul 2016 16:57:04**

---

Was the physical examination performed?

Yes ☒

---

If No, please specify the reason:

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Physical Examination (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:18**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Discharge (Confinement)**

**Form: Physical Examination (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:18**

**Generated On: 20 Jul 2016 16:57:04**

---

Was the physical examination performed? Yes ☒

---

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

---

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

---

Outcome Abnormal ☒

---

Abnormal, please specify CONJUNCTIVAL INJECTION

---

Clinically significant No ☒

---

Not Done False

---

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

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Physical Examination (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:18**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Discharge (Confinement)**

**Form: Physical Examination (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:18**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Discharge (Confinement)**

**Form: Physical Examination (5)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:18**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Discharge (Confinement)**

**Form: Physical Examination (6)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:18**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Discharge (Confinement)**

**Form: Physical Examination (7)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:18**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Discharge (Confinement)**

**Form: Physical Examination (8)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:18**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Discharge (Confinement)**

**Form: Physical Examination (9)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:18**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Discharge (Confinement)**

**Form: Physical Examination (10)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:18**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Discharge (Confinement)**

**Form: Physical Examination (11)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:18**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Discharge (Confinement)**

**Form: Physical Examination (12)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:18**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Discharge (Confinement)**

**Form: Physical Examination (13)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:18**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Discharge (Confinement)**

**Form: Physical Examination (14)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:18**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Discharge (Confinement)**

**Form: Physical Examination (15)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:18**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Discharge (Confinement)**

**Form: Physical Examination (16)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:18**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Discharge (Confinement)**

**Form: Physical Examination (17)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:18**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Discharge (Confinement)**

**Form: Physical Examination (18)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:18**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Discharge (Confinement)**

**Form: Physical Examination (19)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:18**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Discharge (Confinement)**

**Form: Weight**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

Measurement(s) assessed?

Yes ☒

---

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

---

Date of Assessment

14 MAR 2014  
DD/MMM/YYYY

---

Time of assessment

10:37  
hour:min 24-hour clock

---

Weight

76.7  
kg

---

BMI

24.2

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Discharge (Confinement)**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:35:18**

**Generated On: 20 Jul 2016 16:57:04**

---

Was the ECG performed?

Yes ☒

---

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

---

Position

Supine ☒

---

Heart Rate

63  
beats per minute

---

QRS Interval

94  
msec

---

QT Interval

387  
msec

---

QTcB Interval

396  
msec

---

PR Interval

143  
msec

---

QTcF Interval

393  
msec

---

Interpretation

Normal ☒

---

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



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Discharge (Confinement)**

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

**Data signed: (hfarmer1) 27 Mar 2015 14:35:18**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Gas Transfer**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:20**

**Generated On: 20 Jul 2016 16:57:04**

Was the Gas Transfer performed? Yes ☒

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

Category \_\_\_\_\_

Position SITTING

Date of assessment DD/MMM/YYYY 14 MAR 2014

Time of assessment 07:01

DLCO value 27.31  
ml/min/mmHg

KCO value 1.31  
mmol/min/kPa/L

DLCO/VA value 3.69  
mL/min/mmHg/L

Interpretation Normal ☒

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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lung Volume Measurements**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:20**

**Generated On: 20 Jul 2016 16:57:04**

---

Were the Lung Volume Measurements performed? Yes ☒

---

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

---

Category \_\_\_\_\_

---

Position SITTING

---

Date of assessment 14 MAR 2014  
DD/MMM/YYYY

---

Time of assessment 07:10

---

VC value 5.06  
L

---

TLC value 6.58  
L

---

IC value 3.05  
L

---

FRC value 3.53  
L

---

Interpretation Normal ☒

---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lung Volume Measurements**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:20**

**Generated On: 20 Jul 2016 16:57:04**

---

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

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Spirometry with a short-acting bronchodilator**

**Data signed: (hcoleman1) 18 Jun 2015 20:59:09**

**Generated On: 20 Jul 2016 16:57:04**

---

|  |                                      |
|--|--------------------------------------|
| Was the Spirometry with a short-acting bronchodilator performed? | Yes <input checked="" type="radio"/> |
|--|--------------------------------------|

---

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

---

---

|          |   |
|----------|---|
| Category | With short-acting bronchodilator <input checked="" type="radio"/> |
|----------|---|

---

---

|          |         |
|----------|---------|
| Position | SITTING |
|----------|---------|

---

---

|                                   |             |
|-----------------------------------|-------------|
| Date of assessment<br>DD/MMM/YYYY | 14 MAR 2014 |
|-----------------------------------|-------------|

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|                    |       |
|--------------------|-------|
| Time of assessment | 07:37 |
|--------------------|-------|

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|                        |                   |
|------------------------|-------------------|
| Name of bronchodilator | ALBUTEROL SULFATE |
|------------------------|-------------------|

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|      |         |
|------|---------|
| Dose | 180 MCG |
|------|---------|

---

---

|                     |           |
|---------------------|-----------|
| Predicted FVC value | 4.53<br>L |
|---------------------|-----------|

---

---

|                         |           |
|-------------------------|-----------|
| Best measured FVC value | 4.96<br>L |
|-------------------------|-----------|

---

---

|                                |          |
|--------------------------------|----------|
| Percent of predicted FVC value | 109<br>% |
|--------------------------------|----------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Spirometry with a short-acting bronchodilator**

**Data signed: (hcoleman1) 18 Jun 2015 20:59:09**

**Generated On: 20 Jul 2016 16:57:04**

---

|                          |           |
|--------------------------|-----------|
| Best measured FEV1 value | 3.46<br>L |
|--------------------------|-----------|

---

|                      |           |
|----------------------|-----------|
| Predicted FEV1 value | 3.78<br>L |
|----------------------|-----------|

---

|                                 |         |
|---------------------------------|---------|
| Percent of predicted FEV1 value | 91<br>% |
|---------------------------------|---------|

---

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

---

|                 |             |
|-----------------|-------------|
| MEF 25/75 value | 2.24<br>L/s |
|-----------------|-------------|

---

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

---

|                                    |       |
|------------------------------------|-------|
| If Abnormal, Clinical Significance | _____ |
|------------------------------------|-------|

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|  |       |
|--|-------|
| If Not Clinically Significant or Clinically Significant, Please specify the finding(s) | _____ |
|--|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Haematology**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:18**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Discharge (Confinement)**

**Form: Clinical Chemistry**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:18**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Discharge (Confinement)**

**Form: Urine analysis**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:18**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Discharge (Confinement)**

**Form: CO Breath Test**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:18**

**Generated On: 20 Jul 2016 16:57:04**

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|                     |      |
|---------------------|------|
| Assessment not done | True |
|---------------------|------|

---

|   |                                      |
|---|--------------------------------------|
| If Not Done, please specify the reason: | PROCEDURE OMITTED AT<br>TIME OF TASK |
|---|--------------------------------------|

---

|                           |       |
|---------------------------|-------|
| Actual Time of Assessment | <hr/> |
|---------------------------|-------|

---

|        |       |
|--------|-------|
| Result | <hr/> |
|--------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

---

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

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|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

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|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W816724 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 14 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:41 |
|------------------------|-------|

---

|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

---

|            |        |
|------------|--------|
| Battery ID | RC1029 |
|------------|--------|

---

|              |               |
|--------------|---------------|
| Battery Name | TRIGLYCERIDES |
|--------------|---------------|

---

|             |       |
|-------------|-------|
| Lab Test ID | RCT19 |
|-------------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | TRIGLYCERIDES (GPO)                   |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 94                                    |
| Reported Numeric Result           | 94                                    |
| Reference Range low               | 50                                    |
| Reference Range high              | 321                                   |
| 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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

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Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

---

|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

---

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

---

|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

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|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W816724 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 14 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:41 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

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|            |        |
|------------|--------|
| Battery ID | RC1092 |
|------------|--------|

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|              |                 |
|--------------|-----------------|
| Battery Name | FASTING GLUCOSE |
|--------------|-----------------|

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|             |        |
|-------------|--------|
| Lab Test ID | RCT142 |
|-------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | FASTING GLUCOSE                       |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 86                                    |
| Reported Numeric Result           | 86                                    |
| 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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

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Comment

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

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Transmission Type Cumulative ☒

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex M

---

Subject Date of Birth (b) (6)

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☒

---

Accession ID W816724

---

Actual Collection Date 2014 03 14

---

Actual Collection Time 06:41

---

Specimen Condition \_\_\_\_\_

---

Battery ID RC272

---

Battery Name TOTAL CHOLESTEROL

---

Lab Test ID RCT20

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                |
|-----------------------------------|--------------------------------|
| Lab Test Name                     | CHOLESTEROL (HIGH PERFORMANCE) |
| Test ID                           |                                |
| Test Status                       | Done <input type="radio"/>     |
| Reported Text Result              | 133                            |
| Reported Numeric Result           | 133                            |
| Reference Range low               | 150                            |
| Reference Range high              | 264                            |
| 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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Text Result

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

Low ☒

Clinically Significant?

No ☒

Comment

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

Transmission Type Cumulative ☐

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex M

---

Subject Date of Birth (b) (6)

---

Visit Name \_\_\_\_\_

---

Visit Type Scheduled ☐

---

Accession ID W816724

---

Actual Collection Date 2014 03 14

---

Actual Collection Time 06:41

---

Specimen Condition \_\_\_\_\_

---

Battery ID RC9255

---

Battery Name CHEMISTRY PANEL

---

Lab Test ID RCT1

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | TOTAL BILIRUBIN                       |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 0.7                                   |
| Reported Numeric Result           | 0.7                                   |
| 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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (5)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

---

|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

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|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W816724 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 14 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:41 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

---

|            |        |
|------------|--------|
| Battery ID | RC9255 |
|------------|--------|

---

|              |                 |
|--------------|-----------------|
| Battery Name | CHEMISTRY PANEL |
|--------------|-----------------|

---

|             |       |
|-------------|-------|
| Lab Test ID | RCT12 |
|-------------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (5)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                               |
|-----------------------------------|-------------------------------|
| Lab Test Name                     | TOTAL PROTEIN                 |
| Test ID                           |                               |
| Test Status                       | Done <input type="checkbox"/> |
| Reported Text Result              | 7.4                           |
| Reported Numeric Result           | 7.4                           |
| 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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (5)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (6)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

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|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

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|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W816724 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 14 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:41 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

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|            |        |
|------------|--------|
| Battery ID | RC9255 |
|------------|--------|

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|              |                 |
|--------------|-----------------|
| Battery Name | CHEMISTRY PANEL |
|--------------|-----------------|

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|             |       |
|-------------|-------|
| Lab Test ID | RCT13 |
|-------------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (6)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | ALBUMIN                               |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 4.6                                   |
| Reported Numeric Result           | 4.6                                   |
| 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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (6)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (7)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

---

|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W816724 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 14 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:41 |
|------------------------|-------|

---

|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

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|            |        |
|------------|--------|
| Battery ID | RC9255 |
|------------|--------|

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|              |                 |
|--------------|-----------------|
| Battery Name | CHEMISTRY PANEL |
|--------------|-----------------|

---

|             |         |
|-------------|---------|
| Lab Test ID | RCT1407 |
|-------------|---------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (7)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                            |
|-----------------------------------|----------------------------|
| Lab Test Name                     | ALKALINE PHOSPHATASE       |
| Test ID                           |                            |
| Test Status                       | Done <input type="radio"/> |
| Reported Text Result              | 73                         |
| Reported Numeric Result           | 73                         |
| Reference Range low               | 31                         |
| Reference Range high              | 129                        |
| 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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (7)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (8)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

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|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

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|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

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|              |         |
|--------------|---------|
| Accession ID | W816724 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 14 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:41 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

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|            |        |
|------------|--------|
| Battery ID | RC9255 |
|------------|--------|

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|              |                 |
|--------------|-----------------|
| Battery Name | CHEMISTRY PANEL |
|--------------|-----------------|

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|             |         |
|-------------|---------|
| Lab Test ID | RCT1408 |
|-------------|---------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (8)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                               |
|-----------------------------------|-------------------------------|
| Lab Test Name                     | LDH                           |
| Test ID                           |                               |
| Test Status                       | Done <input type="checkbox"/> |
| Reported Text Result              | 151                           |
| Reported Numeric Result           | 151                           |
| 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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (8)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (9)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

---

|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

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|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W816724 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 14 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:41 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

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|            |        |
|------------|--------|
| Battery ID | RC9255 |
|------------|--------|

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|              |                 |
|--------------|-----------------|
| Battery Name | CHEMISTRY PANEL |
|--------------|-----------------|

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|             |       |
|-------------|-------|
| Lab Test ID | RCT15 |
|-------------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (9)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | SERUM SODIUM                          |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 141                                   |
| Reported Numeric Result           | 141                                   |
| 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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (9)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

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Comment

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (10)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

Transmission Type Cumulative ☒

---

Subject ID or Number \_\_\_\_\_

---

Subject Sex M

---

Subject Date of Birth (b) (6)

---

Visit Name \_\_\_\_\_

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Visit Type Scheduled ☒

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Accession ID W816724

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Actual Collection Date 2014 03 14

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Actual Collection Time 06:41

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Specimen Condition \_\_\_\_\_

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Battery ID RC9255

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Battery Name CHEMISTRY PANEL

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Lab Test ID RCT16

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (10)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | SERUM POTASSIUM                       |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 5.2                                   |
| Reported Numeric Result           | 5.2                                   |
| 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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (10)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (11)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

---

|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W816724 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 14 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:41 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

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|            |        |
|------------|--------|
| Battery ID | RC9255 |
|------------|--------|

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|              |                 |
|--------------|-----------------|
| Battery Name | CHEMISTRY PANEL |
|--------------|-----------------|

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|             |       |
|-------------|-------|
| Lab Test ID | RCT29 |
|-------------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (11)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | DIRECT BILIRUBIN                      |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 0.2                                   |
| Reported Numeric Result           | 0.2                                   |
| 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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (11)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

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Comment

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (12)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

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|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

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|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

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|              |         |
|--------------|---------|
| Accession ID | W816724 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 14 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:41 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

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|            |        |
|------------|--------|
| Battery ID | RC9255 |
|------------|--------|

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|              |                 |
|--------------|-----------------|
| Battery Name | CHEMISTRY PANEL |
|--------------|-----------------|

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|             |      |
|-------------|------|
| Lab Test ID | RCT3 |
|-------------|------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (12)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                            |
|-----------------------------------|----------------------------|
| Lab Test Name                     | GGT                        |
| Test ID                           |                            |
| Test Status                       | Done <input type="radio"/> |
| Reported Text Result              | 24                         |
| Reported Numeric Result           | 24                         |
| Reference Range low               | 10                         |
| Reference Range high              | 61                         |
| 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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (12)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

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Clinically Significant?

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Comment

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (13)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

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|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

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|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

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|              |         |
|--------------|---------|
| Accession ID | W816724 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 14 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:41 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

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|            |        |
|------------|--------|
| Battery ID | RC9255 |
|------------|--------|

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|              |                 |
|--------------|-----------------|
| Battery Name | CHEMISTRY PANEL |
|--------------|-----------------|

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|             |        |
|-------------|--------|
| Lab Test ID | RCT392 |
|-------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (13)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

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|               |                           |
|---------------|---------------------------|
| Lab Test Name | CREATININE (RATE BLANKED) |
|---------------|---------------------------|

---

|         |       |
|---------|-------|
| Test ID | <hr/> |
|---------|-------|

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|             |                                       |
|-------------|---------------------------------------|
| Test Status | Done <input checked="" type="radio"/> |
|-------------|---------------------------------------|

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|                      |     |
|----------------------|-----|
| Reported Text Result | 1.3 |
|----------------------|-----|

---

|                         |     |
|-------------------------|-----|
| Reported Numeric Result | 1.3 |
|-------------------------|-----|

---

|                     |     |
|---------------------|-----|
| Reference Range low | 0.5 |
|---------------------|-----|

---

|                      |     |
|----------------------|-----|
| Reference Range high | 1.2 |
|----------------------|-----|

---

|             |       |
|-------------|-------|
| Range Units | MG/DL |
|-------------|-------|

---

|                          |       |
|--------------------------|-------|
| Conventional Text Result | <hr/> |
|--------------------------|-------|

---

|                             |       |
|-----------------------------|-------|
| Conventional Numeric Result | <hr/> |
|-----------------------------|-------|

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|                                  |       |
|----------------------------------|-------|
| Conventional Reference Range Low | <hr/> |
|----------------------------------|-------|

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|                                   |       |
|-----------------------------------|-------|
| Conventional Reference Range High | <hr/> |
|-----------------------------------|-------|

---

|                    |       |
|--------------------|-------|
| Conventional Units | <hr/> |
|--------------------|-------|

---

|                |       |
|----------------|-------|
| SI Text Result | <hr/> |
|----------------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (13)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

High ☒

Clinically Significant?

No ☒

Comment

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (14)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

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|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

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|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W816724 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 14 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:41 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

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|            |        |
|------------|--------|
| Battery ID | RC9255 |
|------------|--------|

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|              |                 |
|--------------|-----------------|
| Battery Name | CHEMISTRY PANEL |
|--------------|-----------------|

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|             |      |
|-------------|------|
| Lab Test ID | RCT4 |
|-------------|------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (14)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                            |
|-----------------------------------|----------------------------|
| Lab Test Name                     | ALT (SGPT)                 |
| Test ID                           |                            |
| Test Status                       | Done <input type="radio"/> |
| Reported Text Result              | 15                         |
| Reported Numeric Result           | 15                         |
| Reference Range low               | 6                          |
| Reference Range high              | 43                         |
| 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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (14)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

---

Comment

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (15)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

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|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

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|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

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|              |         |
|--------------|---------|
| Accession ID | W816724 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 14 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:41 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

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|            |        |
|------------|--------|
| Battery ID | RC9255 |
|------------|--------|

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|              |                 |
|--------------|-----------------|
| Battery Name | CHEMISTRY PANEL |
|--------------|-----------------|

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|             |      |
|-------------|------|
| Lab Test ID | RCT5 |
|-------------|------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (15)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                            |
|-----------------------------------|----------------------------|
| Lab Test Name                     | AST (SGOT)                 |
| Test ID                           |                            |
| Test Status                       | Done <input type="radio"/> |
| Reported Text Result              | 17                         |
| Reported Numeric Result           | 17                         |
| Reference Range low               | 11                         |
| Reference Range high              | 36                         |
| 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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (15)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

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Comment

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (16)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

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|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

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|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

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|              |         |
|--------------|---------|
| Accession ID | W816724 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 14 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:41 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

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|            |        |
|------------|--------|
| Battery ID | RC9255 |
|------------|--------|

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|              |                 |
|--------------|-----------------|
| Battery Name | CHEMISTRY PANEL |
|--------------|-----------------|

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|             |      |
|-------------|------|
| Lab Test ID | RCT6 |
|-------------|------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (16)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | UREA NITROGEN                         |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 22                                    |
| Reported Numeric Result           | 22                                    |
| 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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (16)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

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Alert Flag

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Clinically Significant?

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Comment

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (17)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

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|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

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|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

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|              |         |
|--------------|---------|
| Accession ID | W816724 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 14 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:41 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

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|            |        |
|------------|--------|
| Battery ID | HM1604 |
|------------|--------|

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|              |                                   |
|--------------|-----------------------------------|
| Battery Name | HEMATOLOGY<br>&DIFFERENTIAL PANEL |
|--------------|-----------------------------------|

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|             |       |
|-------------|-------|
| Lab Test ID | HMT10 |
|-------------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (17)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | MONOCYTES                             |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 0.36                                  |
| Reported Numeric Result           | 0.36                                  |
| 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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (17)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

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Comment

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (18)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

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|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

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|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

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|              |         |
|--------------|---------|
| Accession ID | W816724 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 14 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:41 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

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|            |        |
|------------|--------|
| Battery ID | HM1604 |
|------------|--------|

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|              |                                   |
|--------------|-----------------------------------|
| Battery Name | HEMATOLOGY<br>&DIFFERENTIAL PANEL |
|--------------|-----------------------------------|

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|             |        |
|-------------|--------|
| Lab Test ID | HMT100 |
|-------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (18)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | MCH                                   |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 32                                    |
| Reported Numeric Result           | 32                                    |
| 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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (18)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

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Comment

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (19)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

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|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

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|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

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|              |         |
|--------------|---------|
| Accession ID | W816724 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 14 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:41 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

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|            |        |
|------------|--------|
| Battery ID | HM1604 |
|------------|--------|

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|              |                                   |
|--------------|-----------------------------------|
| Battery Name | HEMATOLOGY<br>&DIFFERENTIAL PANEL |
|--------------|-----------------------------------|

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|             |        |
|-------------|--------|
| Lab Test ID | HMT102 |
|-------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (19)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | MCHC                                  |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 34                                    |
| Reported Numeric Result           | 34                                    |
| 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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (19)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

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Alert Flag

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Clinically Significant?

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Comment

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (20)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

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|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

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|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

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|              |         |
|--------------|---------|
| Accession ID | W816724 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 14 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:41 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

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|            |        |
|------------|--------|
| Battery ID | HM1604 |
|------------|--------|

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|              |                                   |
|--------------|-----------------------------------|
| Battery Name | HEMATOLOGY<br>&DIFFERENTIAL PANEL |
|--------------|-----------------------------------|

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|             |       |
|-------------|-------|
| Lab Test ID | HMT11 |
|-------------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (20)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |  |
|-----------------------------------|--|
| Lab Test Name                     | EOSINOPHILS                              |
| Test ID                           |  |
| Test Status                       | Done <input checked="" type="checkbox"/> |
| Reported Text Result              | 0.18                                     |
| Reported Numeric Result           | 0.18                                     |
| 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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (20)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

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Comment

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (21)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

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|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

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|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

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|              |         |
|--------------|---------|
| Accession ID | W816724 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 14 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:41 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

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|            |        |
|------------|--------|
| Battery ID | HM1604 |
|------------|--------|

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|              |                                   |
|--------------|-----------------------------------|
| Battery Name | HEMATOLOGY<br>&DIFFERENTIAL PANEL |
|--------------|-----------------------------------|

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|             |       |
|-------------|-------|
| Lab Test ID | HMT12 |
|-------------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (21)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |  |
|-----------------------------------|--|
| Lab Test Name                     | BASOPHILS                                |
| Test ID                           |  |
| Test Status                       | Done <input checked="" type="checkbox"/> |
| Reported Text Result              | 0.02                                     |
| Reported Numeric Result           | 0.02                                     |
| 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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (21)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

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Clinically Significant?

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Comment

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (22)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

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|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

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|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

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|              |         |
|--------------|---------|
| Accession ID | W816724 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 14 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:41 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

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|            |        |
|------------|--------|
| Battery ID | HM1604 |
|------------|--------|

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|              |                                   |
|--------------|-----------------------------------|
| Battery Name | HEMATOLOGY<br>&DIFFERENTIAL PANEL |
|--------------|-----------------------------------|

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|             |       |
|-------------|-------|
| Lab Test ID | HMT13 |
|-------------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (22)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | PLATELETS                             |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 216                                   |
| Reported Numeric Result           | 216                                   |
| 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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (22)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

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Reported Result Type

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Alert Flag

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Clinically Significant?

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Comment

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (23)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

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|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

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|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

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|              |         |
|--------------|---------|
| Accession ID | W816724 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 14 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:41 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

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|            |        |
|------------|--------|
| Battery ID | HM1604 |
|------------|--------|

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|              |                                   |
|--------------|-----------------------------------|
| Battery Name | HEMATOLOGY<br>&DIFFERENTIAL PANEL |
|--------------|-----------------------------------|

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|             |       |
|-------------|-------|
| Lab Test ID | HMT15 |
|-------------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (23)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | NEUTROPHILS (%)                       |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 28.5                                  |
| Reported Numeric Result           | 28.5                                  |
| 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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (23)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

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Alert Flag

Low ☒

Clinically Significant?

No ☒

Comment

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (24)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

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|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

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|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

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|              |         |
|--------------|---------|
| Accession ID | W816724 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 14 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:41 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

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|            |        |
|------------|--------|
| Battery ID | HM1604 |
|------------|--------|

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|              |                                   |
|--------------|-----------------------------------|
| Battery Name | HEMATOLOGY<br>&DIFFERENTIAL PANEL |
|--------------|-----------------------------------|

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|             |       |
|-------------|-------|
| Lab Test ID | HMT16 |
|-------------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (24)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | LYMPHOCYTES (%)                       |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 62.6                                  |
| Reported Numeric Result           | 62.6                                  |
| 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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (24)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

High ☒

Clinically Significant?

No ☒

Comment

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (25)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

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|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

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|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

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|              |         |
|--------------|---------|
| Accession ID | W816724 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 14 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:41 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

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|            |        |
|------------|--------|
| Battery ID | HM1604 |
|------------|--------|

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|              |                                   |
|--------------|-----------------------------------|
| Battery Name | HEMATOLOGY<br>&DIFFERENTIAL PANEL |
|--------------|-----------------------------------|

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|             |       |
|-------------|-------|
| Lab Test ID | HMT17 |
|-------------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (25)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |  |
|-----------------------------------|--|
| Lab Test Name                     | MONOCYTES (%)                            |
| Test ID                           |  |
| Test Status                       | Done <input checked="" type="checkbox"/> |
| Reported Text Result              | 5.8                                      |
| Reported Numeric Result           | 5.8                                      |
| 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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (25)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

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Comment

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (26)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

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|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

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|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

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|              |         |
|--------------|---------|
| Accession ID | W816724 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 14 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:41 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

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|            |        |
|------------|--------|
| Battery ID | HM1604 |
|------------|--------|

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|              |                                   |
|--------------|-----------------------------------|
| Battery Name | HEMATOLOGY<br>&DIFFERENTIAL PANEL |
|--------------|-----------------------------------|

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|             |       |
|-------------|-------|
| Lab Test ID | HMT18 |
|-------------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (26)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                               |
|-----------------------------------|-------------------------------|
| Lab Test Name                     | EOSINOPHILS (%)               |
| Test ID                           |                               |
| Test Status                       | Done <input type="checkbox"/> |
| Reported Text Result              | 2.8                           |
| Reported Numeric Result           | 2.8                           |
| 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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (26)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

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SI Units

---

Reported Result Type

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Alert Flag

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Clinically Significant?

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Comment

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (27)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

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|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

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|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

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|              |         |
|--------------|---------|
| Accession ID | W816724 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 14 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:41 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

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|            |        |
|------------|--------|
| Battery ID | HM1604 |
|------------|--------|

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|              |                                   |
|--------------|-----------------------------------|
| Battery Name | HEMATOLOGY<br>&DIFFERENTIAL PANEL |
|--------------|-----------------------------------|

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|             |       |
|-------------|-------|
| Lab Test ID | HMT19 |
|-------------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (27)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                            |
|-----------------------------------|----------------------------|
| Lab Test Name                     | BASOPHILS (%)              |
| Test ID                           |                            |
| Test Status                       | Done <input type="radio"/> |
| Reported Text Result              | 0.4                        |
| Reported Numeric Result           | 0.4                        |
| 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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (27)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

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Alert Flag

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Clinically Significant?

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Comment

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (28)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

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|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

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|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

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|              |         |
|--------------|---------|
| Accession ID | W816724 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 14 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:41 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

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|            |        |
|------------|--------|
| Battery ID | HM1604 |
|------------|--------|

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|              |                                   |
|--------------|-----------------------------------|
| Battery Name | HEMATOLOGY<br>&DIFFERENTIAL PANEL |
|--------------|-----------------------------------|

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|             |      |
|-------------|------|
| Lab Test ID | HMT2 |
|-------------|------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (28)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | HEMATOCRIT                            |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 46                                    |
| Reported Numeric Result           | 46                                    |
| Reference Range low               | 39                                    |
| Reference Range high              | 54                                    |
| 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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (28)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

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Clinically Significant?

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Comment

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (29)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

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|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

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|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

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|              |         |
|--------------|---------|
| Accession ID | W816724 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 14 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:41 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

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|            |        |
|------------|--------|
| Battery ID | HM1604 |
|------------|--------|

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|              |                                   |
|--------------|-----------------------------------|
| Battery Name | HEMATOLOGY<br>&DIFFERENTIAL PANEL |
|--------------|-----------------------------------|

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|             |      |
|-------------|------|
| Lab Test ID | HMT3 |
|-------------|------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (29)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | RBC                                   |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 4.9                                   |
| Reported Numeric Result           | 4.9                                   |
| Reference Range low               | 4.5                                   |
| Reference Range high              | 6.4                                   |
| 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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (29)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

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Alert Flag

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Clinically Significant?

---

Comment

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (30)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

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|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

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|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W816724 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 14 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:41 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

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|            |        |
|------------|--------|
| Battery ID | HM1604 |
|------------|--------|

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|              |                                   |
|--------------|-----------------------------------|
| Battery Name | HEMATOLOGY<br>&DIFFERENTIAL PANEL |
|--------------|-----------------------------------|

---

|             |      |
|-------------|------|
| Lab Test ID | HMT4 |
|-------------|------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (30)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                            |
|-----------------------------------|----------------------------|
| Lab Test Name                     | MCV                        |
| Test ID                           |                            |
| Test Status                       | Done <input type="radio"/> |
| Reported Text Result              | 93                         |
| Reported Numeric Result           | 93                         |
| Reference Range low               | 79                         |
| Reference Range high              | 96                         |
| 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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (30)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

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Comment

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (31)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

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|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W816724 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 14 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:41 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

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|            |        |
|------------|--------|
| Battery ID | HM1604 |
|------------|--------|

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|              |                                   |
|--------------|-----------------------------------|
| Battery Name | HEMATOLOGY<br>&DIFFERENTIAL PANEL |
|--------------|-----------------------------------|

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|             |       |
|-------------|-------|
| Lab Test ID | HMT40 |
|-------------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (31)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | HEMOGLOBIN                            |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 15.6                                  |
| Reported Numeric Result           | 15.6                                  |
| Reference Range low               | 12.7                                  |
| Reference Range high              | 18.1                                  |
| 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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (31)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

---

Clinically Significant?

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Comment

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (32)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

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|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

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|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W816724 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 14 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:41 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

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|            |        |
|------------|--------|
| Battery ID | HM1604 |
|------------|--------|

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|              |                                   |
|--------------|-----------------------------------|
| Battery Name | HEMATOLOGY<br>&DIFFERENTIAL PANEL |
|--------------|-----------------------------------|

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|             |      |
|-------------|------|
| Lab Test ID | HMT7 |
|-------------|------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (32)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | WBC                                   |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 6.25                                  |
| Reported Numeric Result           | 6.25                                  |
| 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                    |                                       |

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (32)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (33)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

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|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

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|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W816724 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 14 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:41 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

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|            |        |
|------------|--------|
| Battery ID | HM1604 |
|------------|--------|

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|              |                                   |
|--------------|-----------------------------------|
| Battery Name | HEMATOLOGY<br>&DIFFERENTIAL PANEL |
|--------------|-----------------------------------|

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|             |       |
|-------------|-------|
| Lab Test ID | HMT71 |
|-------------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (33)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (33)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (34)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

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|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

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|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

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|              |         |
|--------------|---------|
| Accession ID | W816724 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 14 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:41 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

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|            |        |
|------------|--------|
| Battery ID | HM1604 |
|------------|--------|

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|              |                                   |
|--------------|-----------------------------------|
| Battery Name | HEMATOLOGY<br>&DIFFERENTIAL PANEL |
|--------------|-----------------------------------|

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|             |      |
|-------------|------|
| Lab Test ID | HMT8 |
|-------------|------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (34)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                            |
|-----------------------------------|----------------------------|
| Lab Test Name                     | NEUTROPHILS                |
| Test ID                           |                            |
| Test Status                       | Done <input type="radio"/> |
| Reported Text Result              | 1.78                       |
| Reported Numeric Result           | 1.78                       |
| 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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (34)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

SI Numeric Result

---

SI Reference Range Low

---

SI Reference Range High

---

SI Units

---

Reported Result Type

---

Alert Flag

Low ☒

Clinically Significant?

No ☒

Comment

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (35)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

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|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

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|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

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|              |         |
|--------------|---------|
| Accession ID | W816724 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 14 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:41 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

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|            |        |
|------------|--------|
| Battery ID | HM1604 |
|------------|--------|

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|              |                                   |
|--------------|-----------------------------------|
| Battery Name | HEMATOLOGY<br>&DIFFERENTIAL PANEL |
|--------------|-----------------------------------|

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|             |      |
|-------------|------|
| Lab Test ID | HMT9 |
|-------------|------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (35)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                                       |
|-----------------------------------|---------------------------------------|
| Lab Test Name                     | LYMPHOCYTES                           |
| Test ID                           |                                       |
| Test Status                       | Done <input checked="" type="radio"/> |
| Reported Text Result              | 3.92                                  |
| Reported Numeric Result           | 3.92                                  |
| 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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (35)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (36)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

---

|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

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|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W816724 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 14 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:41 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

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|            |        |
|------------|--------|
| Battery ID | UA1538 |
|------------|--------|

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|              |                   |
|--------------|-------------------|
| Battery Name | URINE MACRO PANEL |
|--------------|-------------------|

---

|             |       |
|-------------|-------|
| Lab Test ID | UAT10 |
|-------------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (36)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (36)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (37)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

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|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

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|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W816724 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 14 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:41 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

---

|            |        |
|------------|--------|
| Battery ID | UA1538 |
|------------|--------|

---

|              |                   |
|--------------|-------------------|
| Battery Name | URINE MACRO PANEL |
|--------------|-------------------|

---

|             |      |
|-------------|------|
| Lab Test ID | UAT2 |
|-------------|------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (37)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                               |
|-----------------------------------|-------------------------------|
| Lab Test Name                     | UR SPECIFIC GRAVITY           |
| Test ID                           |                               |
| Test Status                       | Done <input type="checkbox"/> |
| Reported Text Result              | 1.005                         |
| Reported Numeric Result           | 1.005                         |
| 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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (37)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (38)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

---

|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

---

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

---

|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W816724 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 14 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:41 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

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|            |        |
|------------|--------|
| Battery ID | UA1538 |
|------------|--------|

---

|              |                   |
|--------------|-------------------|
| Battery Name | URINE MACRO PANEL |
|--------------|-------------------|

---

|             |      |
|-------------|------|
| Lab Test ID | UAT3 |
|-------------|------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (38)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

|                                   |                            |
|-----------------------------------|----------------------------|
| Lab Test Name                     | UR PH                      |
| Test ID                           |                            |
| Test Status                       | Done <input 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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (38)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (39)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

---

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

---

|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

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|              |         |
|--------------|---------|
| Accession ID | W816724 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 14 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:41 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

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|            |        |
|------------|--------|
| Battery ID | UA1538 |
|------------|--------|

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|              |                   |
|--------------|-------------------|
| Battery Name | URINE MACRO PANEL |
|--------------|-------------------|

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|             |       |
|-------------|-------|
| Lab Test ID | UAT43 |
|-------------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (39)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (39)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (40)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

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|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

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|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

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

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|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

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|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

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|              |         |
|--------------|---------|
| Accession ID | W816724 |
|--------------|---------|

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|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 14 |
|------------------------|------------|

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|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:41 |
|------------------------|-------|

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|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

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|            |        |
|------------|--------|
| Battery ID | UA1538 |
|------------|--------|

---

|              |                   |
|--------------|-------------------|
| Battery Name | URINE MACRO PANEL |
|--------------|-------------------|

---

|             |       |
|-------------|-------|
| Lab Test ID | UAT49 |
|-------------|-------|

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (40)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

Lab Test Name


UR PROTEIN

---

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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (40)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (41)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

---

|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

---

|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

---

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

---

|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W816724 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 14 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:41 |
|------------------------|-------|

---

|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

---

|            |        |
|------------|--------|
| Battery ID | UA1538 |
|------------|--------|

---

|              |                   |
|--------------|-------------------|
| Battery Name | URINE MACRO PANEL |
|--------------|-------------------|

---

|             |      |
|-------------|------|
| Lab Test ID | UAT5 |
|-------------|------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (41)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (41)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (42)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

|                   |   |
|-------------------|---|
| Transmission Type | Cumulative <input checked="" type="radio"/> |
|-------------------|---|

---

|                      |       |
|----------------------|-------|
| Subject ID or Number | <hr/> |
|----------------------|-------|

---

|             |   |
|-------------|---|
| Subject Sex | M |
|-------------|---|

---

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

---

|            |       |
|------------|-------|
| Visit Name | <hr/> |
|------------|-------|

---

|            |  |
|------------|--|
| Visit Type | Scheduled <input checked="" type="radio"/> |
|------------|--|

---

|              |         |
|--------------|---------|
| Accession ID | W816724 |
|--------------|---------|

---

|                        |            |
|------------------------|------------|
| Actual Collection Date | 2014 03 14 |
|------------------------|------------|

---

|                        |       |
|------------------------|-------|
| Actual Collection Time | 06:41 |
|------------------------|-------|

---

|                    |       |
|--------------------|-------|
| Specimen Condition | <hr/> |
|--------------------|-------|

---

|            |        |
|------------|--------|
| Battery ID | UA1538 |
|------------|--------|

---

|              |                   |
|--------------|-------------------|
| Battery Name | URINE MACRO PANEL |
|--------------|-------------------|

---

|             |      |
|-------------|------|
| Lab Test ID | UAT7 |
|-------------|------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (42)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Discharge (Confinement)**

**Form: Lab\_BU\_CCLS (42)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:21**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Product administration-mCC**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:42**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Product administration-mCC (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:42**

**Generated On: 20 Jul 2016 16:57:04**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 07 MAR 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 | 06:48 |
|----------------------|-------|

---

|                     |       |
|---------------------|-------|
| Time of butt return | 06:53 |
|---------------------|-------|

---

|                |       |
|----------------|-------|
| 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: 1194**

**Folder: Product Use**

**Form: Product administration-mCC (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:42**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Product administration-mCC (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:42**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 07 MAR 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 | 06:54 |
|----------------------|-------|

---

|                     |       |
|---------------------|-------|
| Time of butt return | 07:02 |
|---------------------|-------|

---

|                |       |
|----------------|-------|
| CC with SODIM? | False |
|----------------|-------|

---

|                    |       |
|--------------------|-------|
| CC not compatible? | False |
|--------------------|-------|

---

|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

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|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-mCC (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:42**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Product administration-mCC (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:42**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 07 MAR 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 | 08:27 |
|----------------------|-------|

---

|                     |       |
|---------------------|-------|
| Time of butt return | 08:34 |
|---------------------|-------|

---

|                |       |
|----------------|-------|
| CC with SODIM? | False |
|----------------|-------|

---

|                    |       |
|--------------------|-------|
| CC not compatible? | False |
|--------------------|-------|

---

|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

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|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-mCC (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:42**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Product administration-mCC (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:42**

**Generated On: 20 Jul 2016 16:57:04**

---

|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 07 MAR 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 | 09:37 |
|----------------------|-------|

---

|                     |       |
|---------------------|-------|
| Time of butt return | 09:43 |
|---------------------|-------|

---

|                |       |
|----------------|-------|
| CC with SODIM? | False |
|----------------|-------|

---

|                    |       |
|--------------------|-------|
| CC not compatible? | False |
|--------------------|-------|

---

|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

---

|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-mCC (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:42**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Product administration-mCC (5)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:42**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 07 MAR 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 | 10:44 |
|----------------------|-------|

---

|                     |       |
|---------------------|-------|
| Time of butt return | 10:51 |
|---------------------|-------|

---

|                |       |
|----------------|-------|
| CC with SODIM? | False |
|----------------|-------|

---

|                    |       |
|--------------------|-------|
| CC not compatible? | False |
|--------------------|-------|

---

|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

---

|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-mCC (5)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:42**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Product administration-mCC (6)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:42**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 07 MAR 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 | 14:38 |
|----------------------|-------|

---

|                     |       |
|---------------------|-------|
| Time of butt return | 14:44 |
|---------------------|-------|

---

|                |       |
|----------------|-------|
| CC with SODIM? | False |
|----------------|-------|

---

|                    |       |
|--------------------|-------|
| CC not compatible? | False |
|--------------------|-------|

---

|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

---

|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

---

|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-mCC (6)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:42**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Product administration-mCC (7)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:42**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 07 MAR 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 | 16:06 |
|----------------------|-------|

---

|                     |       |
|---------------------|-------|
| Time of butt return | 16:16 |
|---------------------|-------|

---

|                |       |
|----------------|-------|
| 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: 1194**

**Folder: Product Use**

**Form: Product administration-mCC (7)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:42**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Product administration-mCC (8)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:42**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 07 MAR 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 | 17:58 |
|----------------------|-------|

---

|                     |       |
|---------------------|-------|
| Time of butt return | 18:03 |
|---------------------|-------|

---

|                |       |
|----------------|-------|
| 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: 1194**

**Folder: Product Use**

**Form: Product administration-mCC (8)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:42**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Product administration-mCC (9)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:42**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 07 MAR 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 | 19:19 |
|----------------------|-------|

---

|                     |       |
|---------------------|-------|
| Time of butt return | 19:27 |
|---------------------|-------|

---

|                |       |
|----------------|-------|
| CC with SODIM? | False |
|----------------|-------|

---

|                    |       |
|--------------------|-------|
| CC not compatible? | False |
|--------------------|-------|

---

|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

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|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

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|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-mCC (9)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:42**

**Generated On: 20 Jul 2016 16:57:04**

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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.

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Product administration-mCC (10)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:42**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 07 MAR 2014 |
|------------------------------------|-------------|

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|       |   |
|-------|---|
| Visit | Day -1 <input checked="" type="radio"/> |
|-------|---|

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|                     |                                      |
|---------------------|--------------------------------------|
| Type of Product Use | mCC <input checked="" type="radio"/> |
|---------------------|--------------------------------------|

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If type of Product Use different from the randomization  
please explain \_\_\_\_\_

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|                      |       |
|----------------------|-------|
| Time of distribution | 20:23 |
|----------------------|-------|

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|                     |       |
|---------------------|-------|
| Time of butt return | 20:34 |
|---------------------|-------|

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|                |       |
|----------------|-------|
| CC with SODIM? | False |
|----------------|-------|

---

|                    |       |
|--------------------|-------|
| CC not compatible? | False |
|--------------------|-------|

---

|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

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|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

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|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-mCC (10)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:42**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Product administration-mCC (11)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:42**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 07 MAR 2014 |
|------------------------------------|-------------|

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|       |   |
|-------|---|
| Visit | Day -1 <input checked="" type="radio"/> |
|-------|---|

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|                     |                                      |
|---------------------|--------------------------------------|
| Type of Product Use | mCC <input checked="" type="radio"/> |
|---------------------|--------------------------------------|

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If type of Product Use different from the randomization  
please explain \_\_\_\_\_

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|                      |       |
|----------------------|-------|
| Time of distribution | 22:01 |
|----------------------|-------|

---

|                     |       |
|---------------------|-------|
| Time of butt return | 22:07 |
|---------------------|-------|

---

|                |       |
|----------------|-------|
| CC with SODIM? | False |
|----------------|-------|

---

|                    |       |
|--------------------|-------|
| CC not compatible? | False |
|--------------------|-------|

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|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

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|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

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|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-mCC (11)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:42**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Product administration-mCC (12)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:42**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 07 MAR 2014 |
|------------------------------------|-------------|

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|       |   |
|-------|---|
| 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 | 22:33 |
|----------------------|-------|

---

|                     |       |
|---------------------|-------|
| Time of butt return | 22:44 |
|---------------------|-------|

---

|                |       |
|----------------|-------|
| CC with SODIM? | False |
|----------------|-------|

---

|                    |       |
|--------------------|-------|
| CC not compatible? | False |
|--------------------|-------|

---

|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

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|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

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|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-mCC (12)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:42**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Product administration-mCC (13)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:42**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 08 MAR 2014 |
|------------------------------------|-------------|

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|       |  |
|-------|--|
| Visit | Day 0 <input checked="" type="radio"/> |
|-------|--|

---

|                     |                                      |
|---------------------|--------------------------------------|
| Type of Product Use | mCC <input checked="" type="radio"/> |
|---------------------|--------------------------------------|

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If type of Product Use different from the randomization  
please explain \_\_\_\_\_

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|                      |       |
|----------------------|-------|
| Time of distribution | 07:28 |
|----------------------|-------|

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|                     |       |
|---------------------|-------|
| Time of butt return | 07:34 |
|---------------------|-------|

---

|                |      |
|----------------|------|
| CC with SODIM? | True |
|----------------|------|

---

|                    |       |
|--------------------|-------|
| CC not compatible? | False |
|--------------------|-------|

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|                     |     |
|---------------------|-----|
| SODIM device number | 167 |
|---------------------|-----|

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|                            |      |
|----------------------------|------|
| SODIM sample holder number | 0213 |
|----------------------------|------|

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|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0167COHP10213001 |
|-------------------|----------------------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-mCC (13)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:42**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Product administration-mCC (14)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:42**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 08 MAR 2014 |
|------------------------------------|-------------|

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|       |  |
|-------|--|
| 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 \_\_\_\_\_

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|                      |       |
|----------------------|-------|
| Time of distribution | 08:27 |
|----------------------|-------|

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|                     |       |
|---------------------|-------|
| Time of butt return | 08:36 |
|---------------------|-------|

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|                |      |
|----------------|------|
| CC with SODIM? | True |
|----------------|------|

---

|                    |       |
|--------------------|-------|
| CC not compatible? | False |
|--------------------|-------|

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|                     |     |
|---------------------|-----|
| SODIM device number | 167 |
|---------------------|-----|

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|                            |      |
|----------------------------|------|
| SODIM sample holder number | 0213 |
|----------------------------|------|

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|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0167COHP10213002 |
|-------------------|----------------------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-mCC (14)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:42**

**Generated On: 20 Jul 2016 16:57:04**

---

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.

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Product administration-mCC (15)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:42**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 08 MAR 2014 |
|------------------------------------|-------------|

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|       |  |
|-------|--|
| Visit | Day 0 <input checked="" type="radio"/> |
|-------|--|

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|                     |                                      |
|---------------------|--------------------------------------|
| Type of Product Use | mCC <input checked="" type="radio"/> |
|---------------------|--------------------------------------|

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If type of Product Use different from the randomization  
please explain \_\_\_\_\_

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|                      |       |
|----------------------|-------|
| Time of distribution | 11:44 |
|----------------------|-------|

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|                     |       |
|---------------------|-------|
| Time of butt return | 11:53 |
|---------------------|-------|

---

|                |      |
|----------------|------|
| CC with SODIM? | True |
|----------------|------|

---

|                    |       |
|--------------------|-------|
| CC not compatible? | False |
|--------------------|-------|

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|                     |     |
|---------------------|-----|
| SODIM device number | 167 |
|---------------------|-----|

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|                            |      |
|----------------------------|------|
| SODIM sample holder number | 0213 |
|----------------------------|------|

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|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0167COHP10213004 |
|-------------------|----------------------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-mCC (15)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:42**

**Generated On: 20 Jul 2016 16:57:04**

---

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.

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Product administration-mCC (16)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:42**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 08 MAR 2014 |
|------------------------------------|-------------|

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|       |  |
|-------|--|
| 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 \_\_\_\_\_

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|                      |       |
|----------------------|-------|
| Time of distribution | 11:54 |
|----------------------|-------|

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|                     |       |
|---------------------|-------|
| Time of butt return | 12:03 |
|---------------------|-------|

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|                |      |
|----------------|------|
| CC with SODIM? | True |
|----------------|------|

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|                    |       |
|--------------------|-------|
| CC not compatible? | False |
|--------------------|-------|

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|                     |     |
|---------------------|-----|
| SODIM device number | 167 |
|---------------------|-----|

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|                            |      |
|----------------------------|------|
| SODIM sample holder number | 0213 |
|----------------------------|------|

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|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0167COHP10213005 |
|-------------------|----------------------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-mCC (16)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:42**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Product administration-mCC (17)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:42**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 08 MAR 2014 |
|------------------------------------|-------------|

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|       |  |
|-------|--|
| 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 \_\_\_\_\_

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|                      |       |
|----------------------|-------|
| Time of distribution | 13:25 |
|----------------------|-------|

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|                     |       |
|---------------------|-------|
| Time of butt return | 13:33 |
|---------------------|-------|

---

|                |      |
|----------------|------|
| CC with SODIM? | True |
|----------------|------|

---

|                    |       |
|--------------------|-------|
| CC not compatible? | False |
|--------------------|-------|

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|                     |     |
|---------------------|-----|
| SODIM device number | 167 |
|---------------------|-----|

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|                            |      |
|----------------------------|------|
| SODIM sample holder number | 0213 |
|----------------------------|------|

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|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0167COHP10213006 |
|-------------------|----------------------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-mCC (17)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:42**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Product administration-mCC (18)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:42**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 08 MAR 2014 |
|------------------------------------|-------------|

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|       |  |
|-------|--|
| 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 \_\_\_\_\_

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|                      |       |
|----------------------|-------|
| Time of distribution | 16:21 |
|----------------------|-------|

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|                     |       |
|---------------------|-------|
| Time of butt return | 16:28 |
|---------------------|-------|

---

|                |      |
|----------------|------|
| CC with SODIM? | True |
|----------------|------|

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|                    |       |
|--------------------|-------|
| CC not compatible? | False |
|--------------------|-------|

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|                     |     |
|---------------------|-----|
| SODIM device number | 167 |
|---------------------|-----|

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|                            |      |
|----------------------------|------|
| SODIM sample holder number | 0213 |
|----------------------------|------|

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|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0167COHP10213007 |
|-------------------|----------------------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-mCC (18)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:42**

**Generated On: 20 Jul 2016 16:57:04**

---

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.

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Product administration-mCC (19)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:42**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 08 MAR 2014 |
|------------------------------------|-------------|

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|       |  |
|-------|--|
| 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 \_\_\_\_\_

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|                      |       |
|----------------------|-------|
| Time of distribution | 17:47 |
|----------------------|-------|

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|                     |       |
|---------------------|-------|
| Time of butt return | 17:54 |
|---------------------|-------|

---

|                |      |
|----------------|------|
| CC with SODIM? | True |
|----------------|------|

---

|                    |       |
|--------------------|-------|
| CC not compatible? | False |
|--------------------|-------|

---

|                     |     |
|---------------------|-----|
| SODIM device number | 167 |
|---------------------|-----|

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|                            |      |
|----------------------------|------|
| SODIM sample holder number | 0213 |
|----------------------------|------|

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|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0167COHP10213008 |
|-------------------|----------------------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-mCC (19)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:42**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Product administration-mCC (20)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:42**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 08 MAR 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 \_\_\_\_\_

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|                      |       |
|----------------------|-------|
| Time of distribution | 19:18 |
|----------------------|-------|

---

|                     |       |
|---------------------|-------|
| Time of butt return | 19:24 |
|---------------------|-------|

---

|                |      |
|----------------|------|
| CC with SODIM? | True |
|----------------|------|

---

|                    |       |
|--------------------|-------|
| CC not compatible? | False |
|--------------------|-------|

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|                     |     |
|---------------------|-----|
| SODIM device number | 167 |
|---------------------|-----|

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|                            |      |
|----------------------------|------|
| SODIM sample holder number | 0213 |
|----------------------------|------|

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|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0167COHP10213009 |
|-------------------|----------------------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-mCC (20)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:42**

**Generated On: 20 Jul 2016 16:57:04**

---

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.

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Product administration-mCC (21)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:42**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 08 MAR 2014 |
|------------------------------------|-------------|

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|       |  |
|-------|--|
| Visit | Day 0 <input checked="" type="radio"/> |
|-------|--|

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|                     |                                      |
|---------------------|--------------------------------------|
| Type of Product Use | mCC <input checked="" type="radio"/> |
|---------------------|--------------------------------------|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

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|                      |       |
|----------------------|-------|
| Time of distribution | 20:54 |
|----------------------|-------|

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|                     |       |
|---------------------|-------|
| Time of butt return | 21:02 |
|---------------------|-------|

---

|                |      |
|----------------|------|
| CC with SODIM? | True |
|----------------|------|

---

|                    |       |
|--------------------|-------|
| CC not compatible? | False |
|--------------------|-------|

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|                     |     |
|---------------------|-----|
| SODIM device number | 167 |
|---------------------|-----|

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|                            |      |
|----------------------------|------|
| SODIM sample holder number | 0213 |
|----------------------------|------|

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|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0167COHP10213010 |
|-------------------|----------------------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-mCC (21)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:42**

**Generated On: 20 Jul 2016 16:57:04**

---

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.

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Product administration-mCC (22)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:42**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 08 MAR 2014 |
|------------------------------------|-------------|

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|       |  |
|-------|--|
| Visit | Day 0 <input checked="" type="radio"/> |
|-------|--|

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|                     |                                      |
|---------------------|--------------------------------------|
| Type of Product Use | mCC <input checked="" type="radio"/> |
|---------------------|--------------------------------------|

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If type of Product Use different from the randomization  
please explain \_\_\_\_\_

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|                      |       |
|----------------------|-------|
| Time of distribution | 22:13 |
|----------------------|-------|

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|                     |       |
|---------------------|-------|
| Time of butt return | 22:21 |
|---------------------|-------|

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|                |      |
|----------------|------|
| CC with SODIM? | True |
|----------------|------|

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|                    |       |
|--------------------|-------|
| CC not compatible? | False |
|--------------------|-------|

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|                     |     |
|---------------------|-----|
| SODIM device number | 167 |
|---------------------|-----|

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|                            |      |
|----------------------------|------|
| SODIM sample holder number | 0213 |
|----------------------------|------|

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|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0167COHP10213011 |
|-------------------|----------------------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-mCC (22)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:42**

**Generated On: 20 Jul 2016 16:57:04**

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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.

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 09 MAR 2014 |
|------------------------------------|-------------|

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|       |  |
|-------|--|
| Visit | Day 1 <input checked="" type="radio"/> |
|-------|--|

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|                     |  |
|---------------------|--|
| Type of Product Use | THS 2.2 Menthol <input checked="" type="radio"/> |
|---------------------|--|

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If type of Product Use different from the randomization  
please explain \_\_\_\_\_

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|                      |       |
|----------------------|-------|
| Time of distribution | 06:56 |
|----------------------|-------|

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|                        |       |
|------------------------|-------|
| Time of product return | 07:01 |
|------------------------|-------|

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|                     |     |
|---------------------|-----|
| SODIM device number | 167 |
|---------------------|-----|

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|                            |      |
|----------------------------|------|
| SODIM sample holder number | 0619 |
|----------------------------|------|

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1933 |
|-------------------------|-------|

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|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 01 |
|--------------------------|----|

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|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0167COHP10619001 |
|-------------------|----------------------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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|              |        |
|--------------|--------|
| Batch Number | B08545 |
|--------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

---

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.

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 09 MAR 2014 |
|------------------------------------|-------------|

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|       |  |
|-------|--|
| Visit | Day 1 <input checked="" type="radio"/> |
|-------|--|

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|                     |  |
|---------------------|--|
| Type of Product Use | THS 2.2 Menthol <input checked="" type="radio"/> |
|---------------------|--|

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If type of Product Use different from the randomization  
please explain \_\_\_\_\_

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|                      |       |
|----------------------|-------|
| Time of distribution | 09:11 |
|----------------------|-------|

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|                        |       |
|------------------------|-------|
| Time of product return | 09:22 |
|------------------------|-------|

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|                     |     |
|---------------------|-----|
| SODIM device number | 167 |
|---------------------|-----|

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|                            |      |
|----------------------------|------|
| SODIM sample holder number | 0619 |
|----------------------------|------|

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1933 |
|-------------------------|-------|

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|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 02 |
|--------------------------|----|

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|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0167COHP10619002 |
|-------------------|----------------------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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|              |        |
|--------------|--------|
| Batch Number | B08545 |
|--------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

---

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.

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 09 MAR 2014 |
|------------------------------------|-------------|

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|       |  |
|-------|--|
| Visit | Day 1 <input checked="" type="radio"/> |
|-------|--|

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|                     |  |
|---------------------|--|
| Type of Product Use | THS 2.2 Menthol <input checked="" type="radio"/> |
|---------------------|--|

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If type of Product Use different from the randomization  
please explain \_\_\_\_\_

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|                      |       |
|----------------------|-------|
| Time of distribution | 13:35 |
|----------------------|-------|

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|                        |       |
|------------------------|-------|
| Time of product return | 13:43 |
|------------------------|-------|

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|                     |     |
|---------------------|-----|
| SODIM device number | 167 |
|---------------------|-----|

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|                            |      |
|----------------------------|------|
| SODIM sample holder number | 0619 |
|----------------------------|------|

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1933 |
|-------------------------|-------|

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|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 03 |
|--------------------------|----|

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|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0167COHP10619003 |
|-------------------|----------------------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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|              |        |
|--------------|--------|
| Batch Number | B08545 |
|--------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

---

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.

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 09 MAR 2014 |
|------------------------------------|-------------|

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|       |  |
|-------|--|
| Visit | Day 1 <input checked="" type="radio"/> |
|-------|--|

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|                     |  |
|---------------------|--|
| Type of Product Use | THS 2.2 Menthol <input checked="" type="radio"/> |
|---------------------|--|

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If type of Product Use different from the randomization  
please explain \_\_\_\_\_

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|                      |       |
|----------------------|-------|
| Time of distribution | 17:18 |
|----------------------|-------|

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|                        |       |
|------------------------|-------|
| Time of product return | 17:28 |
|------------------------|-------|

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|                     |     |
|---------------------|-----|
| SODIM device number | 167 |
|---------------------|-----|

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|                            |      |
|----------------------------|------|
| SODIM sample holder number | 0619 |
|----------------------------|------|

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1933 |
|-------------------------|-------|

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|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 04 |
|--------------------------|----|

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|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0167COHP10619004 |
|-------------------|----------------------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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|              |        |
|--------------|--------|
| Batch Number | B08545 |
|--------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

---

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.

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (5)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 09 MAR 2014 |
|------------------------------------|-------------|

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|       |  |
|-------|--|
| Visit | Day 1 <input checked="" type="radio"/> |
|-------|--|

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|                     |  |
|---------------------|--|
| Type of Product Use | THS 2.2 Menthol <input checked="" type="radio"/> |
|---------------------|--|

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If type of Product Use different from the randomization  
please explain \_\_\_\_\_

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|                      |       |
|----------------------|-------|
| Time of distribution | 18:47 |
|----------------------|-------|

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|                        |       |
|------------------------|-------|
| Time of product return | 18:59 |
|------------------------|-------|

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|                     |     |
|---------------------|-----|
| SODIM device number | 167 |
|---------------------|-----|

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|                            |      |
|----------------------------|------|
| SODIM sample holder number | 0619 |
|----------------------------|------|

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1933 |
|-------------------------|-------|

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|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 05 |
|--------------------------|----|

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|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0167COHP10619005 |
|-------------------|----------------------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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|              |        |
|--------------|--------|
| Batch Number | B08545 |
|--------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (5)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

---

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.

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (6)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 09 MAR 2014 |
|------------------------------------|-------------|

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|       |  |
|-------|--|
| Visit | Day 1 <input checked="" type="radio"/> |
|-------|--|

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|                     |  |
|---------------------|--|
| Type of Product Use | THS 2.2 Menthol <input checked="" type="radio"/> |
|---------------------|--|

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If type of Product Use different from the randomization  
please explain \_\_\_\_\_

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|                      |       |
|----------------------|-------|
| Time of distribution | 20:45 |
|----------------------|-------|

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|                        |       |
|------------------------|-------|
| Time of product return | 20:54 |
|------------------------|-------|

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|                     |     |
|---------------------|-----|
| SODIM device number | 167 |
|---------------------|-----|

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|                            |      |
|----------------------------|------|
| SODIM sample holder number | 0619 |
|----------------------------|------|

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1933 |
|-------------------------|-------|

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|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 06 |
|--------------------------|----|

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|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0167COHP10619006 |
|-------------------|----------------------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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|              |        |
|--------------|--------|
| Batch Number | B08545 |
|--------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (6)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

---

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.

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (7)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 09 MAR 2014 |
|------------------------------------|-------------|

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|       |  |
|-------|--|
| Visit | Day 1 <input checked="" type="radio"/> |
|-------|--|

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|                     |  |
|---------------------|--|
| Type of Product Use | THS 2.2 Menthol <input checked="" type="radio"/> |
|---------------------|--|

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If type of Product Use different from the randomization  
please explain \_\_\_\_\_

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|                      |       |
|----------------------|-------|
| Time of distribution | 22:07 |
|----------------------|-------|

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|                        |       |
|------------------------|-------|
| Time of product return | 22:15 |
|------------------------|-------|

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|                     |     |
|---------------------|-----|
| SODIM device number | 167 |
|---------------------|-----|

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|                            |      |
|----------------------------|------|
| SODIM sample holder number | 0619 |
|----------------------------|------|

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1933 |
|-------------------------|-------|

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|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 07 |
|--------------------------|----|

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|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0167COHP10619007 |
|-------------------|----------------------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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|              |        |
|--------------|--------|
| Batch Number | B08545 |
|--------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (7)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

---

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.

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (8)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 09 MAR 2014 |
|------------------------------------|-------------|

---

|       |  |
|-------|--|
| Visit | Day 1 <input checked="" type="radio"/> |
|-------|--|

---

|                     |  |
|---------------------|--|
| Type of Product Use | THS 2.2 Menthol <input checked="" type="radio"/> |
|---------------------|--|

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If type of Product Use different from the randomization  
please explain \_\_\_\_\_

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|                      |       |
|----------------------|-------|
| Time of distribution | 22:39 |
|----------------------|-------|

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|                        |       |
|------------------------|-------|
| Time of product return | 22:47 |
|------------------------|-------|

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|                     |     |
|---------------------|-----|
| SODIM device number | 167 |
|---------------------|-----|

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|                            |      |
|----------------------------|------|
| SODIM sample holder number | 0619 |
|----------------------------|------|

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1933 |
|-------------------------|-------|

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|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 08 |
|--------------------------|----|

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|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0167COHP10619008 |
|-------------------|----------------------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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|              |        |
|--------------|--------|
| Batch Number | B08545 |
|--------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (8)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

---

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.

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (9)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 10 MAR 2014 |
|------------------------------------|-------------|

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|       |  |
|-------|--|
| Visit | Day 2 <input checked="" type="radio"/> |
|-------|--|

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|                     |  |
|---------------------|--|
| Type of Product Use | THS 2.2 Menthol <input checked="" type="radio"/> |
|---------------------|--|

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If type of Product Use different from the randomization  
please explain \_\_\_\_\_

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|                      |       |
|----------------------|-------|
| Time of distribution | 06:31 |
|----------------------|-------|

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|                        |       |
|------------------------|-------|
| Time of product return | 06:41 |
|------------------------|-------|

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|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

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|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1937 |
|-------------------------|-------|

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|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 01 |
|--------------------------|----|

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|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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|              |        |
|--------------|--------|
| Batch Number | B08545 |
|--------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (9)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

---

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.

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (10)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 10 MAR 2014 |
|------------------------------------|-------------|

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|       |  |
|-------|--|
| Visit | Day 2 <input checked="" type="radio"/> |
|-------|--|

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|                     |  |
|---------------------|--|
| Type of Product Use | THS 2.2 Menthol <input checked="" type="radio"/> |
|---------------------|--|

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If type of Product Use different from the randomization  
please explain \_\_\_\_\_

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|                      |       |
|----------------------|-------|
| Time of distribution | 08:14 |
|----------------------|-------|

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|                        |       |
|------------------------|-------|
| Time of product return | 08:21 |
|------------------------|-------|

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|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

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|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1937 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 02 |
|--------------------------|----|

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|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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|              |        |
|--------------|--------|
| Batch Number | B08545 |
|--------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (10)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

---

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.

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (11)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 10 MAR 2014 |
|------------------------------------|-------------|

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|       |  |
|-------|--|
| Visit | Day 2 <input checked="" type="radio"/> |
|-------|--|

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|                     |  |
|---------------------|--|
| Type of Product Use | THS 2.2 Menthol <input checked="" type="radio"/> |
|---------------------|--|

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If type of Product Use different from the randomization  
please explain \_\_\_\_\_

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|                      |       |
|----------------------|-------|
| Time of distribution | 10:00 |
|----------------------|-------|

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|                        |       |
|------------------------|-------|
| Time of product return | 10:09 |
|------------------------|-------|

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|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

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|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1937 |
|-------------------------|-------|

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|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 03 |
|--------------------------|----|

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|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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|              |        |
|--------------|--------|
| Batch Number | B08545 |
|--------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (11)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

---

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.

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (12)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 10 MAR 2014 |
|------------------------------------|-------------|

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|       |  |
|-------|--|
| Visit | Day 2 <input checked="" type="radio"/> |
|-------|--|

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|                     |  |
|---------------------|--|
| Type of Product Use | THS 2.2 Menthol <input checked="" type="radio"/> |
|---------------------|--|

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If type of Product Use different from the randomization  
please explain \_\_\_\_\_

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|                      |       |
|----------------------|-------|
| Time of distribution | 16:06 |
|----------------------|-------|

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|                        |       |
|------------------------|-------|
| Time of product return | 16:17 |
|------------------------|-------|

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|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

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|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1937 |
|-------------------------|-------|

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|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 04 |
|--------------------------|----|

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|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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|              |        |
|--------------|--------|
| Batch Number | B08545 |
|--------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (12)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (13)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 10 MAR 2014 |
|------------------------------------|-------------|

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|       |  |
|-------|--|
| Visit | Day 2 <input checked="" type="radio"/> |
|-------|--|

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|                     |  |
|---------------------|--|
| Type of Product Use | THS 2.2 Menthol <input checked="" type="radio"/> |
|---------------------|--|

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If type of Product Use different from the randomization  
please explain \_\_\_\_\_

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|                      |       |
|----------------------|-------|
| Time of distribution | 17:22 |
|----------------------|-------|

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|                        |       |
|------------------------|-------|
| Time of product return | 17:32 |
|------------------------|-------|

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|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

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|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1937 |
|-------------------------|-------|

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|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 05 |
|--------------------------|----|

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|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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|              |        |
|--------------|--------|
| Batch Number | B08545 |
|--------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (13)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

---

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.

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (14)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 10 MAR 2014 |
|------------------------------------|-------------|

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|       |  |
|-------|--|
| Visit | Day 2 <input checked="" type="radio"/> |
|-------|--|

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|                     |  |
|---------------------|--|
| Type of Product Use | THS 2.2 Menthol <input checked="" type="radio"/> |
|---------------------|--|

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If type of Product Use different from the randomization  
please explain

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|                      |       |
|----------------------|-------|
| Time of distribution | 18:46 |
|----------------------|-------|

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|                        |       |
|------------------------|-------|
| Time of product return | 18:54 |
|------------------------|-------|

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|                     |  |
|---------------------|--|
| SODIM device number |  |
|---------------------|--|

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|                            |  |
|----------------------------|--|
| SODIM sample holder number |  |
|----------------------------|--|

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1937 |
|-------------------------|-------|

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|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 06 |
|--------------------------|----|

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|                   |  |
|-------------------|--|
| SODIM file number |  |
|-------------------|--|

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|         |  |
|---------|--|
| Comment |  |
|---------|--|

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|              |        |
|--------------|--------|
| Batch Number | B08545 |
|--------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (14)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (15)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 10 MAR 2014 |
|------------------------------------|-------------|

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|       |  |
|-------|--|
| Visit | Day 2 <input checked="" type="radio"/> |
|-------|--|

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|                     |  |
|---------------------|--|
| Type of Product Use | THS 2.2 Menthol <input checked="" type="radio"/> |
|---------------------|--|

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If type of Product Use different from the randomization  
please explain \_\_\_\_\_

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|                      |       |
|----------------------|-------|
| Time of distribution | 20:14 |
|----------------------|-------|

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|                        |       |
|------------------------|-------|
| Time of product return | 20:24 |
|------------------------|-------|

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|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

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|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1937 |
|-------------------------|-------|

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|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 07 |
|--------------------------|----|

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|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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|              |        |
|--------------|--------|
| Batch Number | B08545 |
|--------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (15)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

---

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.

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (16)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 10 MAR 2014 |
|------------------------------------|-------------|

---

|       |  |
|-------|--|
| Visit | Day 2 <input checked="" type="radio"/> |
|-------|--|

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|                     |  |
|---------------------|--|
| Type of Product Use | THS 2.2 Menthol <input checked="" type="radio"/> |
|---------------------|--|

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If type of Product Use different from the randomization  
please explain \_\_\_\_\_

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|                      |       |
|----------------------|-------|
| Time of distribution | 22:06 |
|----------------------|-------|

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|                        |       |
|------------------------|-------|
| Time of product return | 22:15 |
|------------------------|-------|

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|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

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|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1937 |
|-------------------------|-------|

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|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 08 |
|--------------------------|----|

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|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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|              |        |
|--------------|--------|
| Batch Number | B08545 |
|--------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (16)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

---

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.

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (17)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 11 MAR 2014 |
|------------------------------------|-------------|

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|       |                             |
|-------|-----------------------------|
| Visit | Day 3 <input type="radio"/> |
|-------|-----------------------------|

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|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

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If type of Product Use different from the randomization  
please explain \_\_\_\_\_

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|                      |       |
|----------------------|-------|
| Time of distribution | 06:32 |
|----------------------|-------|

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|                        |       |
|------------------------|-------|
| Time of product return | 06:41 |
|------------------------|-------|

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|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

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|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1941 |
|-------------------------|-------|

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|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 01 |
|--------------------------|----|

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|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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|              |        |
|--------------|--------|
| Batch Number | B08545 |
|--------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (17)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

---

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.

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (18)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 11 MAR 2014 |
|------------------------------------|-------------|

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|       |                             |
|-------|-----------------------------|
| Visit | Day 3 <input type="radio"/> |
|-------|-----------------------------|

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|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

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If type of Product Use different from the randomization  
please explain \_\_\_\_\_

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|                      |       |
|----------------------|-------|
| Time of distribution | 06:42 |
|----------------------|-------|

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|                        |       |
|------------------------|-------|
| Time of product return | 06:51 |
|------------------------|-------|

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|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

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|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1941 |
|-------------------------|-------|

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|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 02 |
|--------------------------|----|

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|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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|              |        |
|--------------|--------|
| Batch Number | B08545 |
|--------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (18)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

---

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.

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (19)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 11 MAR 2014 |
|------------------------------------|-------------|

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|       |                             |
|-------|-----------------------------|
| Visit | Day 3 <input type="radio"/> |
|-------|-----------------------------|

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|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

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If type of Product Use different from the randomization  
please explain \_\_\_\_\_

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|                      |       |
|----------------------|-------|
| Time of distribution | 08:39 |
|----------------------|-------|

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|                        |       |
|------------------------|-------|
| Time of product return | 08:48 |
|------------------------|-------|

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|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

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|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1941 |
|-------------------------|-------|

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|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 03 |
|--------------------------|----|

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|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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|              |        |
|--------------|--------|
| Batch Number | B08545 |
|--------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (19)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (20)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 11 MAR 2014 |
|------------------------------------|-------------|

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|       |                             |
|-------|-----------------------------|
| Visit | Day 3 <input type="radio"/> |
|-------|-----------------------------|

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|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

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If type of Product Use different from the randomization  
please explain

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|                      |       |
|----------------------|-------|
| Time of distribution | 09:28 |
|----------------------|-------|

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|                        |       |
|------------------------|-------|
| Time of product return | 09:36 |
|------------------------|-------|

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|                     |       |
|---------------------|-------|
| SODIM device number | <hr/> |
|---------------------|-------|

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|                            |       |
|----------------------------|-------|
| SODIM sample holder number | <hr/> |
|----------------------------|-------|

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1941 |
|-------------------------|-------|

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|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 04 |
|--------------------------|----|

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|                   |       |
|-------------------|-------|
| SODIM file number | <hr/> |
|-------------------|-------|

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|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

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|              |        |
|--------------|--------|
| Batch Number | B08545 |
|--------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (20)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

---

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.

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (21)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 11 MAR 2014 |
|------------------------------------|-------------|

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|       |                             |
|-------|-----------------------------|
| Visit | Day 3 <input type="radio"/> |
|-------|-----------------------------|

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---

|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

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If type of Product Use different from the randomization  
please explain \_\_\_\_\_

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|                      |       |
|----------------------|-------|
| Time of distribution | 10:36 |
|----------------------|-------|

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|                        |       |
|------------------------|-------|
| Time of product return | 10:47 |
|------------------------|-------|

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|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

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|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1941 |
|-------------------------|-------|

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|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 05 |
|--------------------------|----|

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|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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|              |        |
|--------------|--------|
| Batch Number | B08545 |
|--------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (21)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

---

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.

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (22)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 11 MAR 2014 |
|------------------------------------|-------------|

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|       |                             |
|-------|-----------------------------|
| Visit | Day 3 <input type="radio"/> |
|-------|-----------------------------|

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|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

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If type of Product Use different from the randomization  
please explain

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|                      |       |
|----------------------|-------|
| Time of distribution | 11:08 |
|----------------------|-------|

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|                        |       |
|------------------------|-------|
| Time of product return | 11:17 |
|------------------------|-------|

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|                     |       |
|---------------------|-------|
| SODIM device number | <hr/> |
|---------------------|-------|

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|                            |       |
|----------------------------|-------|
| SODIM sample holder number | <hr/> |
|----------------------------|-------|

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1941 |
|-------------------------|-------|

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|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 06 |
|--------------------------|----|

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|                   |       |
|-------------------|-------|
| SODIM file number | <hr/> |
|-------------------|-------|

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|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

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|              |        |
|--------------|--------|
| Batch Number | B08545 |
|--------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (22)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

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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.

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (23)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 11 MAR 2014 |
|------------------------------------|-------------|

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|       |                             |
|-------|-----------------------------|
| Visit | Day 3 <input type="radio"/> |
|-------|-----------------------------|

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|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

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If type of Product Use different from the randomization  
please explain

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|                      |       |
|----------------------|-------|
| Time of distribution | 13:00 |
|----------------------|-------|

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|                        |       |
|------------------------|-------|
| Time of product return | 13:02 |
|------------------------|-------|

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|                     |       |
|---------------------|-------|
| SODIM device number | <hr/> |
|---------------------|-------|

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|                            |       |
|----------------------------|-------|
| SODIM sample holder number | <hr/> |
|----------------------------|-------|

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1941 |
|-------------------------|-------|

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|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 07 |
|--------------------------|----|

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|                   |       |
|-------------------|-------|
| SODIM file number | <hr/> |
|-------------------|-------|

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|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

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|              |        |
|--------------|--------|
| Batch Number | B08545 |
|--------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (23)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

---

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.

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (24)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 11 MAR 2014 |
|------------------------------------|-------------|

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|       |                             |
|-------|-----------------------------|
| Visit | Day 3 <input type="radio"/> |
|-------|-----------------------------|

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|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

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If type of Product Use different from the randomization  
please explain

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|                      |       |
|----------------------|-------|
| Time of distribution | 14:03 |
|----------------------|-------|

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|                        |       |
|------------------------|-------|
| Time of product return | 14:10 |
|------------------------|-------|

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|                     |       |
|---------------------|-------|
| SODIM device number | <hr/> |
|---------------------|-------|

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|                            |       |
|----------------------------|-------|
| SODIM sample holder number | <hr/> |
|----------------------------|-------|

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1941 |
|-------------------------|-------|

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|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 08 |
|--------------------------|----|

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|                   |       |
|-------------------|-------|
| SODIM file number | <hr/> |
|-------------------|-------|

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|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

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|              |        |
|--------------|--------|
| Batch Number | B08545 |
|--------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (24)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (25)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 11 MAR 2014 |
|------------------------------------|-------------|

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|       |                             |
|-------|-----------------------------|
| Visit | Day 3 <input type="radio"/> |
|-------|-----------------------------|

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|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

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If type of Product Use different from the randomization  
please explain \_\_\_\_\_

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|                      |       |
|----------------------|-------|
| Time of distribution | 16:19 |
|----------------------|-------|

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|                        |       |
|------------------------|-------|
| Time of product return | 16:28 |
|------------------------|-------|

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|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

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|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1941 |
|-------------------------|-------|

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|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 09 |
|--------------------------|----|

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|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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|              |        |
|--------------|--------|
| Batch Number | B08545 |
|--------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (25)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

---

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.

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (26)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 11 MAR 2014 |
|------------------------------------|-------------|

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|       |                             |
|-------|-----------------------------|
| Visit | Day 3 <input type="radio"/> |
|-------|-----------------------------|

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|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

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If type of Product Use different from the randomization  
please explain

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|                      |       |
|----------------------|-------|
| Time of distribution | 18:28 |
|----------------------|-------|

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|                        |       |
|------------------------|-------|
| Time of product return | 18:34 |
|------------------------|-------|

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|                     |       |
|---------------------|-------|
| SODIM device number | <hr/> |
|---------------------|-------|

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|                            |       |
|----------------------------|-------|
| SODIM sample holder number | <hr/> |
|----------------------------|-------|

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1941 |
|-------------------------|-------|

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|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 10 |
|--------------------------|----|

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|                   |       |
|-------------------|-------|
| SODIM file number | <hr/> |
|-------------------|-------|

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|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

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|              |        |
|--------------|--------|
| Batch Number | B08545 |
|--------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (26)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (27)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 11 MAR 2014 |
|------------------------------------|-------------|

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|       |                             |
|-------|-----------------------------|
| Visit | Day 3 <input type="radio"/> |
|-------|-----------------------------|

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|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

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If type of Product Use different from the randomization  
please explain \_\_\_\_\_

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|                      |       |
|----------------------|-------|
| Time of distribution | 19:26 |
|----------------------|-------|

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|                        |       |
|------------------------|-------|
| Time of product return | 19:37 |
|------------------------|-------|

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|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

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|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1941 |
|-------------------------|-------|

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|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 11 |
|--------------------------|----|

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|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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|              |        |
|--------------|--------|
| Batch Number | B08545 |
|--------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (27)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (28)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 11 MAR 2014 |
|------------------------------------|-------------|

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|       |                             |
|-------|-----------------------------|
| Visit | Day 3 <input type="radio"/> |
|-------|-----------------------------|

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|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

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If type of Product Use different from the randomization  
please explain \_\_\_\_\_

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|                      |       |
|----------------------|-------|
| Time of distribution | 20:47 |
|----------------------|-------|

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|                        |       |
|------------------------|-------|
| Time of product return | 21:03 |
|------------------------|-------|

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|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

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|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1941 |
|-------------------------|-------|

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|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 12 |
|--------------------------|----|

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|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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|              |        |
|--------------|--------|
| Batch Number | B08545 |
|--------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (28)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

---

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.

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (29)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 11 MAR 2014 |
|------------------------------------|-------------|

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|       |                             |
|-------|-----------------------------|
| Visit | Day 3 <input type="radio"/> |
|-------|-----------------------------|

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|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

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If type of Product Use different from the randomization  
please explain \_\_\_\_\_

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|                      |       |
|----------------------|-------|
| Time of distribution | 22:29 |
|----------------------|-------|

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|                        |       |
|------------------------|-------|
| Time of product return | 22:40 |
|------------------------|-------|

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|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

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|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1941 |
|-------------------------|-------|

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|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 13 |
|--------------------------|----|

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|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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|              |        |
|--------------|--------|
| Batch Number | B08545 |
|--------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (29)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

---

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.

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (30)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 12 MAR 2014 |
|------------------------------------|-------------|

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|       |                             |
|-------|-----------------------------|
| Visit | Day 4 <input type="radio"/> |
|-------|-----------------------------|

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|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

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If type of Product Use different from the randomization  
please explain \_\_\_\_\_

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|                      |       |
|----------------------|-------|
| Time of distribution | 06:38 |
|----------------------|-------|

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|                        |       |
|------------------------|-------|
| Time of product return | 06:47 |
|------------------------|-------|

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|                     |     |
|---------------------|-----|
| SODIM device number | 167 |
|---------------------|-----|

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|                            |      |
|----------------------------|------|
| SODIM sample holder number | 0619 |
|----------------------------|------|

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1943 |
|-------------------------|-------|

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|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 01 |
|--------------------------|----|

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|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0167COHP10619009 |
|-------------------|----------------------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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|              |        |
|--------------|--------|
| Batch Number | B08545 |
|--------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (30)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

---

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.

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (31)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 12 MAR 2014 |
|------------------------------------|-------------|

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|       |                             |
|-------|-----------------------------|
| Visit | Day 4 <input type="radio"/> |
|-------|-----------------------------|

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|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

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If type of Product Use different from the randomization  
please explain \_\_\_\_\_

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|                      |       |
|----------------------|-------|
| Time of distribution | 08:14 |
|----------------------|-------|

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|                        |       |
|------------------------|-------|
| Time of product return | 08:23 |
|------------------------|-------|

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|                     |     |
|---------------------|-----|
| SODIM device number | 167 |
|---------------------|-----|

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|                            |      |
|----------------------------|------|
| SODIM sample holder number | 0619 |
|----------------------------|------|

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1943 |
|-------------------------|-------|

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|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 02 |
|--------------------------|----|

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|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0167COHP10619010 |
|-------------------|----------------------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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|              |        |
|--------------|--------|
| Batch Number | B08545 |
|--------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (31)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (32)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 12 MAR 2014 |
|------------------------------------|-------------|

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|       |                             |
|-------|-----------------------------|
| Visit | Day 4 <input type="radio"/> |
|-------|-----------------------------|

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|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

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If type of Product Use different from the randomization  
please explain \_\_\_\_\_

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|                      |       |
|----------------------|-------|
| Time of distribution | 10:26 |
|----------------------|-------|

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|                        |       |
|------------------------|-------|
| Time of product return | 10:32 |
|------------------------|-------|

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|                     |     |
|---------------------|-----|
| SODIM device number | 167 |
|---------------------|-----|

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|                            |      |
|----------------------------|------|
| SODIM sample holder number | 0619 |
|----------------------------|------|

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1943 |
|-------------------------|-------|

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|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 03 |
|--------------------------|----|

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|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0167COHP10619010 |
|-------------------|----------------------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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|              |        |
|--------------|--------|
| Batch Number | B08545 |
|--------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (32)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (33)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 12 MAR 2014 |
|------------------------------------|-------------|

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|       |                             |
|-------|-----------------------------|
| Visit | Day 4 <input type="radio"/> |
|-------|-----------------------------|

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|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

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If type of Product Use different from the randomization  
please explain \_\_\_\_\_

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|                      |       |
|----------------------|-------|
| Time of distribution | 11:34 |
|----------------------|-------|

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|                        |       |
|------------------------|-------|
| Time of product return | 11:49 |
|------------------------|-------|

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|                     |     |
|---------------------|-----|
| SODIM device number | 167 |
|---------------------|-----|

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|                            |      |
|----------------------------|------|
| SODIM sample holder number | 0619 |
|----------------------------|------|

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1943 |
|-------------------------|-------|

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|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 04 |
|--------------------------|----|

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|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0167COHP10619011 |
|-------------------|----------------------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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|              |        |
|--------------|--------|
| Batch Number | B08545 |
|--------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (33)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

---

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.

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (34)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 12 MAR 2014 |
|------------------------------------|-------------|

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|       |                             |
|-------|-----------------------------|
| Visit | Day 4 <input type="radio"/> |
|-------|-----------------------------|

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|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

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If type of Product Use different from the randomization  
please explain \_\_\_\_\_

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|                      |       |
|----------------------|-------|
| Time of distribution | 11:50 |
|----------------------|-------|

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|                        |       |
|------------------------|-------|
| Time of product return | 12:00 |
|------------------------|-------|

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|                     |     |
|---------------------|-----|
| SODIM device number | 167 |
|---------------------|-----|

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|                            |      |
|----------------------------|------|
| SODIM sample holder number | 0619 |
|----------------------------|------|

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1943 |
|-------------------------|-------|

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|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 05 |
|--------------------------|----|

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|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0167COHP10619012 |
|-------------------|----------------------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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|              |        |
|--------------|--------|
| Batch Number | B08545 |
|--------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (34)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (35)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 12 MAR 2014 |
|------------------------------------|-------------|

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|       |                             |
|-------|-----------------------------|
| Visit | Day 4 <input type="radio"/> |
|-------|-----------------------------|

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|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

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If type of Product Use different from the randomization  
please explain \_\_\_\_\_

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|                      |       |
|----------------------|-------|
| Time of distribution | 17:59 |
|----------------------|-------|

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|                        |       |
|------------------------|-------|
| Time of product return | 18:14 |
|------------------------|-------|

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|                     |     |
|---------------------|-----|
| SODIM device number | 167 |
|---------------------|-----|

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|                            |      |
|----------------------------|------|
| SODIM sample holder number | 0619 |
|----------------------------|------|

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1943 |
|-------------------------|-------|

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|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 06 |
|--------------------------|----|

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|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0167COHP10619013 |
|-------------------|----------------------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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|              |        |
|--------------|--------|
| Batch Number | B08545 |
|--------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (35)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (36)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 12 MAR 2014 |
|------------------------------------|-------------|

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|       |                             |
|-------|-----------------------------|
| Visit | Day 4 <input type="radio"/> |
|-------|-----------------------------|

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|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

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If type of Product Use different from the randomization  
please explain \_\_\_\_\_

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|                      |       |
|----------------------|-------|
| Time of distribution | 19:29 |
|----------------------|-------|

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|                        |       |
|------------------------|-------|
| Time of product return | 19:42 |
|------------------------|-------|

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|                     |     |
|---------------------|-----|
| SODIM device number | 167 |
|---------------------|-----|

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|                            |      |
|----------------------------|------|
| SODIM sample holder number | 0619 |
|----------------------------|------|

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1943 |
|-------------------------|-------|

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|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 07 |
|--------------------------|----|

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|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0167COHP10619014 |
|-------------------|----------------------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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|              |        |
|--------------|--------|
| Batch Number | B08545 |
|--------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (36)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (37)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 12 MAR 2014 |
|------------------------------------|-------------|

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|       |                             |
|-------|-----------------------------|
| Visit | Day 4 <input type="radio"/> |
|-------|-----------------------------|

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|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

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If type of Product Use different from the randomization  
please explain \_\_\_\_\_

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|                      |       |
|----------------------|-------|
| Time of distribution | 21:12 |
|----------------------|-------|

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|                        |       |
|------------------------|-------|
| Time of product return | 21:21 |
|------------------------|-------|

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|                     |     |
|---------------------|-----|
| SODIM device number | 167 |
|---------------------|-----|

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|                            |      |
|----------------------------|------|
| SODIM sample holder number | 0619 |
|----------------------------|------|

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1943 |
|-------------------------|-------|

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|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 08 |
|--------------------------|----|

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|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0167COHP10619015 |
|-------------------|----------------------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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|              |        |
|--------------|--------|
| Batch Number | B08545 |
|--------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (37)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

---

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.

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (38)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 12 MAR 2014 |
|------------------------------------|-------------|

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|       |                             |
|-------|-----------------------------|
| Visit | Day 4 <input type="radio"/> |
|-------|-----------------------------|

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|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

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If type of Product Use different from the randomization  
please explain \_\_\_\_\_

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|                      |       |
|----------------------|-------|
| Time of distribution | 22:31 |
|----------------------|-------|

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|                        |       |
|------------------------|-------|
| Time of product return | 22:41 |
|------------------------|-------|

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|                     |     |
|---------------------|-----|
| SODIM device number | 167 |
|---------------------|-----|

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|                            |      |
|----------------------------|------|
| SODIM sample holder number | 0619 |
|----------------------------|------|

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1943 |
|-------------------------|-------|

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|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 09 |
|--------------------------|----|

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|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0167COHP10619016 |
|-------------------|----------------------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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|              |        |
|--------------|--------|
| Batch Number | B08545 |
|--------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (38)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (39)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 13 MAR 2014 |
|------------------------------------|-------------|

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|       |                             |
|-------|-----------------------------|
| Visit | Day 5 <input type="radio"/> |
|-------|-----------------------------|

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|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

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If type of Product Use different from the randomization  
please explain \_\_\_\_\_

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|                      |       |
|----------------------|-------|
| Time of distribution | 06:43 |
|----------------------|-------|

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|                        |       |
|------------------------|-------|
| Time of product return | 07:02 |
|------------------------|-------|

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|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

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|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1949 |
|-------------------------|-------|

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|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 01 |
|--------------------------|----|

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|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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|              |        |
|--------------|--------|
| Batch Number | B08545 |
|--------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (39)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (40)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 13 MAR 2014 |
|------------------------------------|-------------|

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|       |                             |
|-------|-----------------------------|
| Visit | Day 5 <input type="radio"/> |
|-------|-----------------------------|

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|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

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If type of Product Use different from the randomization  
please explain \_\_\_\_\_

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|                      |       |
|----------------------|-------|
| Time of distribution | 08:04 |
|----------------------|-------|

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|                        |       |
|------------------------|-------|
| Time of product return | 08:16 |
|------------------------|-------|

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|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

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|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1949 |
|-------------------------|-------|

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|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 02 |
|--------------------------|----|

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|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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|              |        |
|--------------|--------|
| Batch Number | B08545 |
|--------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (40)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

---

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.

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (41)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 13 MAR 2014 |
|------------------------------------|-------------|

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|       |                             |
|-------|-----------------------------|
| Visit | Day 5 <input type="radio"/> |
|-------|-----------------------------|

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|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

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If type of Product Use different from the randomization  
please explain

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|                      |       |
|----------------------|-------|
| Time of distribution | 11:53 |
|----------------------|-------|

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|                        |       |
|------------------------|-------|
| Time of product return | 12:03 |
|------------------------|-------|

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|                     |       |
|---------------------|-------|
| SODIM device number | <hr/> |
|---------------------|-------|

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|                            |       |
|----------------------------|-------|
| SODIM sample holder number | <hr/> |
|----------------------------|-------|

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1949 |
|-------------------------|-------|

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|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 03 |
|--------------------------|----|

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|                   |       |
|-------------------|-------|
| SODIM file number | <hr/> |
|-------------------|-------|

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|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

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|              |        |
|--------------|--------|
| Batch Number | B08545 |
|--------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (41)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (42)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 13 MAR 2014 |
|------------------------------------|-------------|

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|       |                             |
|-------|-----------------------------|
| Visit | Day 5 <input type="radio"/> |
|-------|-----------------------------|

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|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

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If type of Product Use different from the randomization  
please explain \_\_\_\_\_

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|                      |       |
|----------------------|-------|
| Time of distribution | 13:33 |
|----------------------|-------|

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|                        |       |
|------------------------|-------|
| Time of product return | 13:40 |
|------------------------|-------|

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|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

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|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1949 |
|-------------------------|-------|

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|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 04 |
|--------------------------|----|

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|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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|              |        |
|--------------|--------|
| Batch Number | B08545 |
|--------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (42)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (43)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 13 MAR 2014 |
|------------------------------------|-------------|

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|       |                             |
|-------|-----------------------------|
| Visit | Day 5 <input type="radio"/> |
|-------|-----------------------------|

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|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

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If type of Product Use different from the randomization  
please explain

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|                      |       |
|----------------------|-------|
| Time of distribution | 16:09 |
|----------------------|-------|

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|                        |       |
|------------------------|-------|
| Time of product return | 16:15 |
|------------------------|-------|

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|                     |       |
|---------------------|-------|
| SODIM device number | <hr/> |
|---------------------|-------|

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|                            |       |
|----------------------------|-------|
| SODIM sample holder number | <hr/> |
|----------------------------|-------|

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1949 |
|-------------------------|-------|

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|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 05 |
|--------------------------|----|

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|                   |       |
|-------------------|-------|
| SODIM file number | <hr/> |
|-------------------|-------|

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|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

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|              |        |
|--------------|--------|
| Batch Number | B08545 |
|--------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (43)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

---

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.

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (44)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 13 MAR 2014 |
|------------------------------------|-------------|

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|       |                             |
|-------|-----------------------------|
| Visit | Day 5 <input type="radio"/> |
|-------|-----------------------------|

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|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

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If type of Product Use different from the randomization  
please explain \_\_\_\_\_

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|                      |       |
|----------------------|-------|
| Time of distribution | 17:31 |
|----------------------|-------|

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|                        |       |
|------------------------|-------|
| Time of product return | 17:39 |
|------------------------|-------|

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|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

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|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1949 |
|-------------------------|-------|

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|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 06 |
|--------------------------|----|

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|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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|              |        |
|--------------|--------|
| Batch Number | B08545 |
|--------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (44)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

---

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.

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (45)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 13 MAR 2014 |
|------------------------------------|-------------|

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|       |                             |
|-------|-----------------------------|
| Visit | Day 5 <input type="radio"/> |
|-------|-----------------------------|

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|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

---

If type of Product Use different from the randomization  
please explain

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|                      |       |
|----------------------|-------|
| Time of distribution | 19:55 |
|----------------------|-------|

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|                        |       |
|------------------------|-------|
| Time of product return | 20:09 |
|------------------------|-------|

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|                     |       |
|---------------------|-------|
| SODIM device number | <hr/> |
|---------------------|-------|

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|                            |       |
|----------------------------|-------|
| SODIM sample holder number | <hr/> |
|----------------------------|-------|

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1949 |
|-------------------------|-------|

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|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 07 |
|--------------------------|----|

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|                   |       |
|-------------------|-------|
| SODIM file number | <hr/> |
|-------------------|-------|

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|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

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|              |        |
|--------------|--------|
| Batch Number | B08545 |
|--------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (45)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (46)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 13 MAR 2014 |
|------------------------------------|-------------|

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|       |                             |
|-------|-----------------------------|
| Visit | Day 5 <input type="radio"/> |
|-------|-----------------------------|

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|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

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If type of Product Use different from the randomization  
please explain \_\_\_\_\_

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|                      |       |
|----------------------|-------|
| Time of distribution | 21:39 |
|----------------------|-------|

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|                        |       |
|------------------------|-------|
| Time of product return | 21:47 |
|------------------------|-------|

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|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

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|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1949 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 08 |
|--------------------------|----|

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|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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|              |        |
|--------------|--------|
| Batch Number | B08545 |
|--------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (46)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (47)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 13 MAR 2014 |
|------------------------------------|-------------|

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---

|       |                             |
|-------|-----------------------------|
| Visit | Day 5 <input type="radio"/> |
|-------|-----------------------------|

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---

|                     |                                       |
|---------------------|---------------------------------------|
| Type of Product Use | THS 2.2 Menthol <input type="radio"/> |
|---------------------|---------------------------------------|

---

If type of Product Use different from the randomization  
please explain \_\_\_\_\_

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|                      |       |
|----------------------|-------|
| Time of distribution | 22:41 |
|----------------------|-------|

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|                        |       |
|------------------------|-------|
| Time of product return | 22:50 |
|------------------------|-------|

---

---

|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

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---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

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---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1949 |
|-------------------------|-------|

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|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 09 |
|--------------------------|----|

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|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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|              |        |
|--------------|--------|
| Batch Number | B08545 |
|--------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (47)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (48)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 14 MAR 2014 |
|------------------------------------|-------------|

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---

|       |                             |
|-------|-----------------------------|
| 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

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---

|                      |       |
|----------------------|-------|
| Time of distribution | 07:41 |
|----------------------|-------|

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|                        |       |
|------------------------|-------|
| Time of product return | 07:50 |
|------------------------|-------|

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|                     |       |
|---------------------|-------|
| SODIM device number | <hr/> |
|---------------------|-------|

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|                            |       |
|----------------------------|-------|
| SODIM sample holder number | <hr/> |
|----------------------------|-------|

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | <hr/> |
|-------------------------|-------|

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---

|                          |       |
|--------------------------|-------|
| Tobacco plug vial number | <hr/> |
|--------------------------|-------|

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---

|                   |       |
|-------------------|-------|
| SODIM file number | <hr/> |
|-------------------|-------|

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|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

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|              |        |
|--------------|--------|
| Batch Number | B08545 |
|--------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (48)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (49)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 14 MAR 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 | 09:13 |
|----------------------|-------|

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|                        |       |
|------------------------|-------|
| Time of product return | 09:22 |
|------------------------|-------|

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|                     |       |
|---------------------|-------|
| SODIM device number | <hr/> |
|---------------------|-------|

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | <hr/> |
|----------------------------|-------|

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | <hr/> |
|-------------------------|-------|

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|                          |       |
|--------------------------|-------|
| Tobacco plug vial number | <hr/> |
|--------------------------|-------|

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|                   |       |
|-------------------|-------|
| SODIM file number | <hr/> |
|-------------------|-------|

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|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

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|              |        |
|--------------|--------|
| Batch Number | B08545 |
|--------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (49)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (50)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 14 MAR 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 \_\_\_\_\_

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|                      |       |
|----------------------|-------|
| Time of distribution | 10:14 |
|----------------------|-------|

---

|                        |       |
|------------------------|-------|
| Time of product return | 10:22 |
|------------------------|-------|

---

|                     |       |
|---------------------|-------|
| SODIM device number | _____ |
|---------------------|-------|

---

|                            |       |
|----------------------------|-------|
| SODIM sample holder number | _____ |
|----------------------------|-------|

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | _____ |
|-------------------------|-------|

---

|                          |       |
|--------------------------|-------|
| Tobacco plug vial number | _____ |
|--------------------------|-------|

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|                   |       |
|-------------------|-------|
| SODIM file number | _____ |
|-------------------|-------|

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|         |       |
|---------|-------|
| Comment | _____ |
|---------|-------|

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|              |        |
|--------------|--------|
| Batch Number | B08545 |
|--------------|--------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (50)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (51)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

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|                                    |             |
|------------------------------------|-------------|
| Date of product use<br>DD/MMM/YYYY | 06 MAR 2014 |
|------------------------------------|-------------|

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---

|       |                              |
|-------|------------------------------|
| 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 |
|---|--------------|

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---

|                      |       |
|----------------------|-------|
| Time of distribution | 15:35 |
|----------------------|-------|

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|                        |       |
|------------------------|-------|
| Time of product return | <hr/> |
|------------------------|-------|

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---

|                     |       |
|---------------------|-------|
| 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/> |
|---------|-------|

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---

|              |        |
|--------------|--------|
| Batch Number | B08545 |
|--------------|--------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Folder: Product Use**

**Form: Product administration-THS menthol (51)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:45**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: HST 4 hours (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:55**

**Generated On: 20 Jul 2016 16:57:04**

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|       |                              |
|-------|------------------------------|
| Visit | Day 30 <input type="radio"/> |
|-------|------------------------------|

---

|          |      |
|----------|------|
| Not Done | True |
|----------|------|

---

|                             |                                  |
|-----------------------------|----------------------------------|
| If Not Done, please specify | SUBJECT WAS EARLY<br>TERMINATION |
|-----------------------------|----------------------------------|

---

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

---

|  |  |
|--|--|
| SODIM device distribution time<br>hour:min 24-hour clock |  |
|--|--|

---

|  |  |
|--|--|
| SODIM device collection time<br>hour:min 24-hour clock |  |
|--|--|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: HST 4 hours (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:55**

**Generated On: 20 Jul 2016 16:57:04**

---

|       |   |
|-------|---|
| Visit | Day 60 <input checked="" type="radio"/> |
|-------|---|

---

|          |      |
|----------|------|
| Not Done | True |
|----------|------|

---

|                             |                                  |
|-----------------------------|----------------------------------|
| If Not Done, please specify | SUBJECT WAS EARLY<br>TERMINATION |
|-----------------------------|----------------------------------|

---

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

---

|  |       |
|--|-------|
| SODIM device distribution time<br>hour:min 24-hour clock | <hr/> |
|--|-------|

---

|  |       |
|--|-------|
| SODIM device collection time<br>hour:min 24-hour clock | <hr/> |
|--|-------|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: HST 4 hours (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:55**

**Generated On: 20 Jul 2016 16:57:04**

---

Visit

Day 90 ☒

---

Not Done

True

---

If Not Done, please specify

SUBJECT WAS EARLY  
TERMINATION

---

Date  
DD/MMM/YYYY

---

SODIM device distribution time  
hour:min 24-hour clock

---

SODIM device collection time

hour:min 24-hour clock

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for mCC (1)**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Topography files status for mCC (2)**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Topography files status for mCC (3)**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Topography files status for mCC (4)**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Topography files status for mCC (5)**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Topography files status for mCC (6)**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Topography files status for mCC (7)**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Topography files status for mCC (8)**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Topography files status for mCC (9)**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Topography files status for mCC (10)**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Topography files status for mCC (11)**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Topography files status for mCC (12)**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Topography files status for mCC (13)**

**Generated On: 20 Jul 2016 16:57:04**

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0167COHP10213001 |
|-------------------|----------------------|

---

|             |  |
|-------------|--|
| File Status | Accepted  |
|-------------|--|

---

|                          |       |
|--------------------------|-------|
| Rejection / Error reason | <hr/> |
|--------------------------|-------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 29 AUG 2014 |
|---------------------------------|-------------|

---

|          |  |
|----------|--|
| Operator | Thierry Bachmann  |
|----------|--|

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|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

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|                      |       |
|----------------------|-------|
| Modified File Number | <hr/> |
|----------------------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for mCC (14)**

**Generated On: 20 Jul 2016 16:57:04**

---

|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0167COHP10213002 |
|-------------------|----------------------|

---

|             |  |
|-------------|--|
| File Status | Accepted  |
|-------------|--|

---

|                          |       |
|--------------------------|-------|
| Rejection / Error reason | <hr/> |
|--------------------------|-------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 29 AUG 2014 |
|---------------------------------|-------------|

---

|          |  |
|----------|--|
| Operator | Thierry Bachmann  |
|----------|--|

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|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

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|                      |       |
|----------------------|-------|
| Modified File Number | <hr/> |
|----------------------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for mCC (15)**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0167COHP10213004 |
|-------------------|----------------------|

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|-------------|---|
| File Status | Error  |
|-------------|---|


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|--------------------------|---------------|
| Rejection / Error reason | NB. PUFFS < 3 |
|--------------------------|---------------|

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|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 29 AUG 2014 |
|---------------------------------|-------------|

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|          |  |
|----------|--|
| Operator | Thierry Bachmann  |
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| Comment | <hr/> |
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| Modified File Number | <hr/> |
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for mCC (16)**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0167COHP10213005 |
|-------------------|----------------------|

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|             |   |
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| File Status | Error  |
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| Rejection / Error reason | INVERSED PIPE |
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|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 29 AUG 2014 |
|---------------------------------|-------------|

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|          |  |
|----------|--|
| Operator | Thierry Bachmann  |
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| Comment | <hr/> |
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| Modified File Number | <hr/> |
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for mCC (17)**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0167COHP10213006 |
|-------------------|----------------------|

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|             |  |
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| File Status | Accepted  |
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| Rejection / Error reason | <hr/> |
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| Date of analysis<br>DD/MMM/YYYY | 29 AUG 2014 |
|---------------------------------|-------------|

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|          |  |
|----------|--|
| Operator | Thierry Bachmann  |
|----------|--|

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| Comment | <hr/> |
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| Modified File Number | <hr/> |
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for mCC (18)**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0167COHP10213007 |
|-------------------|----------------------|

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|             |  |
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| File Status | Accepted  |
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| Rejection / Error reason | <hr/> |
|--------------------------|-------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 29 AUG 2014 |
|---------------------------------|-------------|

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|          |  |
|----------|--|
| Operator | Thierry Bachmann  |
|----------|--|

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| Comment | <hr/> |
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| Modified File Number | <hr/> |
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for mCC (19)**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0167COHP10213008 |
|-------------------|----------------------|

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|             |  |
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| File Status | Accepted  |
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| Rejection / Error reason | <hr/> |
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| Date of analysis<br>DD/MMM/YYYY | 29 AUG 2014 |
|---------------------------------|-------------|

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|          |  |
|----------|--|
| Operator | Thierry Bachmann  |
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| Comment | <hr/> |
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| Modified File Number | <hr/> |
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for mCC (20)**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0167COHP10213009 |
|-------------------|----------------------|

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|             |  |
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| File Status | Accepted  |
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| Rejection / Error reason | <hr/> |
|--------------------------|-------|

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| Date of analysis<br>DD/MMM/YYYY | 29 AUG 2014 |
|---------------------------------|-------------|

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|          |  |
|----------|--|
| Operator | Thierry Bachmann  |
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| Comment | <hr/> |
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|----------------------|-------|
| Modified File Number | <hr/> |
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for mCC (21)**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0167COHP10213010 |
|-------------------|----------------------|

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|             |   |
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| File Status | Accepted <input checked="" type="radio"/> |
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| Rejection / Error reason | <hr/> |
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| Date of analysis<br>DD/MMM/YYYY | 29 AUG 2014 |
|---------------------------------|-------------|

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|          |   |
|----------|---|
| Operator | Thierry Bachmann <input checked="" type="radio"/> |
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| Comment | <hr/> |
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| Modified File Number | <hr/> |
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**


**Form: Topography files status for mCC (22)**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0167COHP10213011 |
|-------------------|----------------------|

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|             |  |
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| File Status | Accepted  |
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| Rejection / Error reason | <hr/> |
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| Date of analysis<br>DD/MMM/YYYY | 29 AUG 2014 |
|---------------------------------|-------------|

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|          |  |
|----------|--|
| Operator | Thierry Bachmann  |
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| Comment | <hr/> |
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| Modified File Number | <hr/> |
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for mCC (23)**

**Generated On: 20 Jul 2016 16:57:04**

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SODIM file number

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File Status

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Rejection / Error reason

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Date of analysis  
DD/MMM/YYYY

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Operator

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Comment

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Modified File Number

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for mCC (24)**

**Generated On: 20 Jul 2016 16:57:04**

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SODIM file number

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File Status

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Rejection / Error reason

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Date of analysis  
DD/MMM/YYYY

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Operator

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Comment

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Modified File Number

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for mCC (25)**

**Generated On: 20 Jul 2016 16:57:04**

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SODIM file number

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File Status

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Rejection / Error reason

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Date of analysis  
DD/MMM/YYYY

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Operator

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Comment

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Modified File Number

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for mCC (26)**

**Generated On: 20 Jul 2016 16:57:04**

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SODIM file number

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File Status

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Rejection / Error reason

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Date of analysis  
DD/MMM/YYYY

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Operator

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Comment

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Modified File Number

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for mCC (27)**

**Generated On: 20 Jul 2016 16:57:04**

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SODIM file number

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File Status

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Rejection / Error reason

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Date of analysis  
DD/MMM/YYYY

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Operator

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Comment

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Modified File Number

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for mCC (28)**

**Generated On: 20 Jul 2016 16:57:04**

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SODIM file number

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File Status

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Rejection / Error reason

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Date of analysis  
DD/MMM/YYYY

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Operator

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Comment

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Modified File Number

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for mCC (29)**

**Generated On: 20 Jul 2016 16:57:04**

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SODIM file number

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File Status

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Rejection / Error reason

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Date of analysis  
DD/MMM/YYYY

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Operator

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Comment

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Modified File Number

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for mCC (30)**

**Generated On: 20 Jul 2016 16:57:04**

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SODIM file number

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File Status

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Rejection / Error reason

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Date of analysis  
DD/MMM/YYYY

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Operator

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Comment

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Modified File Number

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for THS menthol (1)**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0167COHP10619001 |
|-------------------|----------------------|

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| File Status | Accepted <input checked="" type="radio"/> |
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| Rejection / Error reason | <hr/> |
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|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 29 AUG 2014 |
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|          |   |
|----------|---|
| Operator | Thierry Bachmann <input checked="" type="radio"/> |
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| Comment | <hr/> |
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| Modified File Number | <hr/> |
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for THS menthol (2)**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0167COHP10619002 |
|-------------------|----------------------|

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|             |   |
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| File Status | Accepted <input checked="" type="radio"/> |
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| Rejection / Error reason | <hr/> |
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|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 29 AUG 2014 |
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|          |   |
|----------|---|
| Operator | Thierry Bachmann <input checked="" type="radio"/> |
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| Comment | <hr/> |
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| Modified File Number | <hr/> |
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for THS menthol (3)**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0167COHP10619003 |
|-------------------|----------------------|

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|             |   |
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| File Status | Accepted <input checked="" type="radio"/> |
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| Rejection / Error reason | <hr/> |
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| Date of analysis<br>DD/MMM/YYYY | 29 AUG 2014 |
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|          |   |
|----------|---|
| Operator | Thierry Bachmann <input checked="" type="radio"/> |
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| Comment | <hr/> |
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| Modified File Number | <hr/> |
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for THS menthol (4)**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0167COHP10619004 |
|-------------------|----------------------|

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|             |   |
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| File Status | Accepted <input checked="" type="radio"/> |
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| Rejection / Error reason | <hr/> |
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| Date of analysis<br>DD/MMM/YYYY | 29 AUG 2014 |
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|          |   |
|----------|---|
| Operator | Thierry Bachmann <input checked="" type="radio"/> |
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| Comment | <hr/> |
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| Modified File Number | <hr/> |
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for THS menthol (5)**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0167COHP10619005 |
|-------------------|----------------------|

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|             |   |
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| File Status | Accepted <input checked="" type="radio"/> |
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| Rejection / Error reason | <hr/> |
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| Date of analysis<br>DD/MMM/YYYY | 29 AUG 2014 |
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|          |   |
|----------|---|
| Operator | Thierry Bachmann <input checked="" type="radio"/> |
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| Comment | <hr/> |
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| Modified File Number | <hr/> |
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for THS menthol (6)**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0167COHP10619006 |
|-------------------|----------------------|

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|             |   |
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| File Status | Accepted <input checked="" type="radio"/> |
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| Rejection / Error reason | <hr/> |
|--------------------------|-------|

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|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 29 AUG 2014 |
|---------------------------------|-------------|

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|          |   |
|----------|---|
| Operator | Thierry Bachmann <input checked="" type="radio"/> |
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| Comment | <hr/> |
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| Modified File Number | <hr/> |
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for THS menthol (7)**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0167COHP10619007 |
|-------------------|----------------------|

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|             |   |
|-------------|---|
| File Status | Accepted <input checked="" type="radio"/> |
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| Rejection / Error reason | <hr/> |
|--------------------------|-------|

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|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 29 AUG 2014 |
|---------------------------------|-------------|

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|          |   |
|----------|---|
| Operator | Thierry Bachmann <input checked="" type="radio"/> |
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| Comment | <hr/> |
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|----------------------|-------|
| Modified File Number | <hr/> |
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for THS menthol (8)**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0167COHP10619008 |
|-------------------|----------------------|

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|             |   |
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| File Status | Accepted <input checked="" type="radio"/> |
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| Rejection / Error reason | <hr/> |
|--------------------------|-------|

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|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 29 AUG 2014 |
|---------------------------------|-------------|

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|          |   |
|----------|---|
| Operator | Thierry Bachmann <input checked="" type="radio"/> |
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| Comment | <hr/> |
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| Modified File Number | <hr/> |
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for THS menthol (9)**

**Generated On: 20 Jul 2016 16:57:04**

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SODIM file number

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File Status

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Rejection / Error reason

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Date of analysis  
DD/MMM/YYYY

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Operator

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Comment

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Modified File Number

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for THS menthol (10)**

**Generated On: 20 Jul 2016 16:57:04**

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SODIM file number

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File Status

---

Rejection / Error reason

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Date of analysis  
DD/MMM/YYYY

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Operator

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Comment

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Modified File Number

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for THS menthol (11)**

**Generated On: 20 Jul 2016 16:57:04**

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SODIM file number

---

File Status

---

Rejection / Error reason

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Date of analysis  
DD/MMM/YYYY

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Operator

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Comment

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Modified File Number

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for THS menthol (12)**

**Generated On: 20 Jul 2016 16:57:04**

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SODIM file number

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File Status

---

Rejection / Error reason

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Date of analysis  
DD/MMM/YYYY

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Operator

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Comment

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Modified File Number

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for THS menthol (13)**

**Generated On: 20 Jul 2016 16:57:04**

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SODIM file number

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File Status

---

Rejection / Error reason

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Date of analysis  
DD/MMM/YYYY

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Operator

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Comment

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Modified File Number

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for THS menthol (14)**

**Generated On: 20 Jul 2016 16:57:04**

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SODIM file number

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File Status

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Rejection / Error reason

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Date of analysis  
DD/MMM/YYYY

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Operator

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Comment

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Modified File Number

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for THS menthol (15)**

**Generated On: 20 Jul 2016 16:57:04**

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SODIM file number

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File Status

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Rejection / Error reason

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Date of analysis  
DD/MMM/YYYY

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Operator

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Comment

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Modified File Number

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for THS menthol (16)**

**Generated On: 20 Jul 2016 16:57:04**

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SODIM file number

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File Status

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Rejection / Error reason

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Date of analysis  
DD/MMM/YYYY

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Operator

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Comment

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Modified File Number

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for THS menthol (17)**

**Generated On: 20 Jul 2016 16:57:04**

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SODIM file number

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File Status

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Rejection / Error reason

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Date of analysis  
DD/MMM/YYYY

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Operator

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Comment

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Modified File Number

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for THS menthol (18)**

**Generated On: 20 Jul 2016 16:57:04**

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SODIM file number

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File Status

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Rejection / Error reason

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Date of analysis  
DD/MMM/YYYY

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Operator

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Comment

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Modified File Number

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for THS menthol (19)**

**Generated On: 20 Jul 2016 16:57:04**

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SODIM file number

---

File Status

---

Rejection / Error reason

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Date of analysis  
DD/MMM/YYYY

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Operator

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Comment

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Modified File Number

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for THS menthol (20)**

**Generated On: 20 Jul 2016 16:57:04**

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SODIM file number

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File Status

---

Rejection / Error reason

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Date of analysis  
DD/MMM/YYYY

---

Operator

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Comment

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Modified File Number

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for THS menthol (21)**

**Generated On: 20 Jul 2016 16:57:04**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

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Comment

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Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for THS menthol (22)**

**Generated On: 20 Jul 2016 16:57:04**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

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Operator

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Comment

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Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for THS menthol (23)**

**Generated On: 20 Jul 2016 16:57:04**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

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Comment

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Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for THS menthol (24)**

**Generated On: 20 Jul 2016 16:57:04**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

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Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for THS menthol (25)**

**Generated On: 20 Jul 2016 16:57:04**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

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Operator

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Comment

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Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for THS menthol (26)**

**Generated On: 20 Jul 2016 16:57:04**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

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Comment

---

Modified File Number

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for THS menthol (27)**

**Generated On: 20 Jul 2016 16:57:04**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

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Comment

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Modified File Number

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for THS menthol (28)**

**Generated On: 20 Jul 2016 16:57:04**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

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Comment

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Modified File Number

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for THS menthol (29)**

**Generated On: 20 Jul 2016 16:57:04**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for THS menthol (30)**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0167COHP10619009 |
|-------------------|----------------------|

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|             |   |
|-------------|---|
| File Status | Accepted <input checked="" type="radio"/> |
|-------------|---|

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|                          |       |
|--------------------------|-------|
| Rejection / Error reason | <hr/> |
|--------------------------|-------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 29 AUG 2014 |
|---------------------------------|-------------|

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|          |   |
|----------|---|
| Operator | Thierry Bachmann <input checked="" type="radio"/> |
|----------|---|

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|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

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|                      |       |
|----------------------|-------|
| Modified File Number | <hr/> |
|----------------------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for THS menthol (33)**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0167COHP10619011 |
|-------------------|----------------------|

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|             |   |
|-------------|---|
| File Status | Accepted <input checked="" type="radio"/> |
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|                          |       |
|--------------------------|-------|
| Rejection / Error reason | <hr/> |
|--------------------------|-------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 29 AUG 2014 |
|---------------------------------|-------------|

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|          |   |
|----------|---|
| Operator | Thierry Bachmann <input checked="" type="radio"/> |
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|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

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|                      |       |
|----------------------|-------|
| Modified File Number | <hr/> |
|----------------------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for THS menthol (34)**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0167COHP10619012 |
|-------------------|----------------------|

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|             |   |
|-------------|---|
| File Status | Accepted <input checked="" type="radio"/> |
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|                          |       |
|--------------------------|-------|
| Rejection / Error reason | <hr/> |
|--------------------------|-------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 29 AUG 2014 |
|---------------------------------|-------------|

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|          |   |
|----------|---|
| Operator | Thierry Bachmann <input checked="" type="radio"/> |
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|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

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|                      |       |
|----------------------|-------|
| Modified File Number | <hr/> |
|----------------------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for THS menthol (35)**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0167COHP10619013 |
|-------------------|----------------------|

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|             |   |
|-------------|---|
| File Status | Accepted <input checked="" type="radio"/> |
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|                          |       |
|--------------------------|-------|
| Rejection / Error reason | <hr/> |
|--------------------------|-------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 29 AUG 2014 |
|---------------------------------|-------------|

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|          |   |
|----------|---|
| Operator | Thierry Bachmann <input checked="" type="radio"/> |
|----------|---|

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|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

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|                      |       |
|----------------------|-------|
| Modified File Number | <hr/> |
|----------------------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for THS menthol (36)**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0167COHP10619014 |
|-------------------|----------------------|

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|             |   |
|-------------|---|
| File Status | Accepted <input checked="" type="radio"/> |
|-------------|---|

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|                          |       |
|--------------------------|-------|
| Rejection / Error reason | <hr/> |
|--------------------------|-------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 29 AUG 2014 |
|---------------------------------|-------------|

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|          |   |
|----------|---|
| Operator | Thierry Bachmann <input checked="" type="radio"/> |
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|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

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|                      |       |
|----------------------|-------|
| Modified File Number | <hr/> |
|----------------------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for THS menthol (37)**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0167COHP10619015 |
|-------------------|----------------------|

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|             |   |
|-------------|---|
| File Status | Accepted <input checked="" type="radio"/> |
|-------------|---|

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|                          |       |
|--------------------------|-------|
| Rejection / Error reason | <hr/> |
|--------------------------|-------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 29 AUG 2014 |
|---------------------------------|-------------|

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|          |   |
|----------|---|
| Operator | Thierry Bachmann <input checked="" type="radio"/> |
|----------|---|

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|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

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|                      |       |
|----------------------|-------|
| Modified File Number | <hr/> |
|----------------------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for THS menthol (38)**

**Generated On: 20 Jul 2016 16:57:04**

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|                   |                      |
|-------------------|----------------------|
| SODIM file number | 08DY0167COHP10619016 |
|-------------------|----------------------|

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|             |   |
|-------------|---|
| File Status | Accepted <input checked="" type="radio"/> |
|-------------|---|

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|                          |       |
|--------------------------|-------|
| Rejection / Error reason | <hr/> |
|--------------------------|-------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 29 AUG 2014 |
|---------------------------------|-------------|

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|          |   |
|----------|---|
| Operator | Thierry Bachmann <input checked="" type="radio"/> |
|----------|---|

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|         |       |
|---------|-------|
| Comment | <hr/> |
|---------|-------|

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|                      |       |
|----------------------|-------|
| Modified File Number | <hr/> |
|----------------------|-------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for THS menthol (39)**

**Generated On: 20 Jul 2016 16:57:04**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

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Operator

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Comment

---

Modified File Number

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for THS menthol (40)**

**Generated On: 20 Jul 2016 16:57:04**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

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Operator

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Comment

---

Modified File Number

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for THS menthol (41)**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Topography files status for THS menthol (42)**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Topography files status for THS menthol (43)**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Topography files status for THS menthol (44)**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Topography files status for THS menthol (45)**

**Generated On: 20 Jul 2016 16:57:04**

---

SODIM file number

---

File Status

---

Rejection / Error reason

---

Date of analysis  
DD/MMM/YYYY

---

Operator

---

Comment

---

Modified File Number

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Topography files status for THS menthol (46)**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Topography files status for THS menthol (47)**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Topography files status for THS menthol (48)**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Topography files status for THS menthol (49)**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Topography files status for THS menthol (50)**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Topography files status for THS menthol (51)**

**Generated On: 20 Jul 2016 16:57:04**

---

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: 1194**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (1)**

**Generated On: 20 Jul 2016 16:57:04**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1933 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 01 |
|--------------------------|----|

---

|       |   |
|-------|---|
| Level | 0  |
|-------|---|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1933_01_00I7.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 23 JUN 2014 |
|---------------------------------|-------------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (2)**

**Generated On: 20 Jul 2016 16:57:04**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1933 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 02 |
|--------------------------|----|

---

|       |                                    |
|-------|------------------------------------|
| Level | 0 <input checked="" type="radio"/> |
|-------|------------------------------------|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1933_02_HJFC.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 23 JUN 2014 |
|---------------------------------|-------------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (3)**

**Generated On: 20 Jul 2016 16:57:04**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1933 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 03 |
|--------------------------|----|

---

|       |                                    |
|-------|------------------------------------|
| Level | 0 <input checked="" type="radio"/> |
|-------|------------------------------------|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1933_03_MW36.JPG |
|-------------------|-------------------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 23 JUN 2014 |
|---------------------------------|-------------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (4)**

**Generated On: 20 Jul 2016 16:57:04**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1933 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 04 |
|--------------------------|----|

---

|       |   |
|-------|---|
| Level | 0  |
|-------|---|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1933_04_M1QC.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 23 JUN 2014 |
|---------------------------------|-------------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (5)**

**Generated On: 20 Jul 2016 16:57:04**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1933 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 05 |
|--------------------------|----|

---

|       |                                    |
|-------|------------------------------------|
| Level | 0 <input checked="" type="radio"/> |
|-------|------------------------------------|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1933_05_KL0Y.JPG |
|-------------------|-------------------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 23 JUN 2014 |
|---------------------------------|-------------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (6)**

**Generated On: 20 Jul 2016 16:57:04**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1933 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 06 |
|--------------------------|----|

---

|       |                                    |
|-------|------------------------------------|
| Level | 0 <input checked="" type="radio"/> |
|-------|------------------------------------|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1933_06_1YU2.JPG |
|-------------------|-------------------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 23 JUN 2014 |
|---------------------------------|-------------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (7)**

**Generated On: 20 Jul 2016 16:57:04**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1933 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 07 |
|--------------------------|----|

---

|       |                         |
|-------|-------------------------|
| Level | 0 <input type="radio"/> |
|-------|-------------------------|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1933_07_8XFV.JPG |
|-------------------|-------------------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 23 JUN 2014 |
|---------------------------------|-------------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (8)**

**Generated On: 20 Jul 2016 16:57:04**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1933 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 08 |
|--------------------------|----|

---

|       |   |
|-------|---|
| Level | 0  |
|-------|---|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1933_08_PMIH.JPG |
|-------------------|-------------------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 23 JUN 2014 |
|---------------------------------|-------------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (1)**

**Generated On: 20 Jul 2016 16:57:04**

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1937 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 01 |
|--------------------------|----|

---

|       |   |
|-------|---|
| Level | 0  |
|-------|---|

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|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

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|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1937_01_RIO0.JPG |
|-------------------|-------------------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 23 JUN 2014 |
|---------------------------------|-------------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (2)**

**Generated On: 20 Jul 2016 16:57:04**

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1937 |
|-------------------------|-------|

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|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 02 |
|--------------------------|----|

---

|       |                                    |
|-------|------------------------------------|
| Level | 0 <input checked="" type="radio"/> |
|-------|------------------------------------|

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|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

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|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1937_02_8GWF.JPG |
|-------------------|-------------------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 23 JUN 2014 |
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (3)**

**Generated On: 20 Jul 2016 16:57:04**

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1937 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 03 |
|--------------------------|----|

---

|       |   |
|-------|---|
| Level | 0  |
|-------|---|

---

|             |       |
|-------------|-------|
| Observation | <hr/> |
|-------------|-------|

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|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1937_03_8QK9.JPG |
|-------------------|-------------------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 23 JUN 2014 |
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (4)**

**Generated On: 20 Jul 2016 16:57:04**

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1937 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 04 |
|--------------------------|----|

---

|       |   |
|-------|---|
| Level | 0  |
|-------|---|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

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|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1937_04_V5JW.JPG |
|-------------------|-------------------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 23 JUN 2014 |
|---------------------------------|-------------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (5)**

**Generated On: 20 Jul 2016 16:57:04**

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1937 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 05 |
|--------------------------|----|

---

|       |                                    |
|-------|------------------------------------|
| Level | 0 <input checked="" type="radio"/> |
|-------|------------------------------------|

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|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

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|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1937_05_PAER.JPG |
|-------------------|-------------------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 23 JUN 2014 |
|---------------------------------|-------------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (6)**

**Generated On: 20 Jul 2016 16:57:04**

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1937 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 06 |
|--------------------------|----|

---

|       |                                    |
|-------|------------------------------------|
| Level | 0 <input checked="" type="radio"/> |
|-------|------------------------------------|

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|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

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|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1937_06_XVET.JPG |
|-------------------|-------------------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 23 JUN 2014 |
|---------------------------------|-------------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (7)**

**Generated On: 20 Jul 2016 16:57:04**

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1937 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 07 |
|--------------------------|----|

---

|       |   |
|-------|---|
| Level | 0  |
|-------|---|

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|             |       |
|-------------|-------|
| Observation | <hr/> |
|-------------|-------|

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|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1937_07_IV40.JPG |
|-------------------|-------------------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 23 JUN 2014 |
|---------------------------------|-------------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (8)**

**Generated On: 20 Jul 2016 16:57:04**

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1937 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 08 |
|--------------------------|----|

---

|       |   |
|-------|---|
| Level | 0  |
|-------|---|

---

|             |       |
|-------------|-------|
| Observation | <hr/> |
|-------------|-------|

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|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1937_08_S3ON.JPG |
|-------------------|-------------------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 23 JUN 2014 |
|---------------------------------|-------------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (1)**

**Generated On: 20 Jul 2016 16:57:04**

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1941 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 01 |
|--------------------------|----|

---

|       |                                    |
|-------|------------------------------------|
| Level | 0 <input checked="" type="radio"/> |
|-------|------------------------------------|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

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|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1941_01_1S21.JPG |
|-------------------|-------------------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 23 JUN 2014 |
|---------------------------------|-------------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (2)**

**Generated On: 20 Jul 2016 16:57:04**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1941 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 02 |
|--------------------------|----|

---

|       |                                    |
|-------|------------------------------------|
| Level | 0 <input checked="" type="radio"/> |
|-------|------------------------------------|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

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|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1941_02_L6PT.JPG |
|-------------------|-------------------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 23 JUN 2014 |
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (3)**

**Generated On: 20 Jul 2016 16:57:04**

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1941 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 03 |
|--------------------------|----|

---

|       |                                    |
|-------|------------------------------------|
| Level | 0 <input checked="" type="radio"/> |
|-------|------------------------------------|

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|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

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|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1941_03_XGF9.JPG |
|-------------------|-------------------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 23 JUN 2014 |
|---------------------------------|-------------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (4)**

**Generated On: 20 Jul 2016 16:57:04**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1941 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 04 |
|--------------------------|----|

---

|       |                                    |
|-------|------------------------------------|
| Level | 0 <input checked="" type="radio"/> |
|-------|------------------------------------|

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|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

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|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1941_04_ISIO.JPG |
|-------------------|-------------------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 23 JUN 2014 |
|---------------------------------|-------------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (5)**

**Generated On: 20 Jul 2016 16:57:04**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1941 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 05 |
|--------------------------|----|

---

|       |                                    |
|-------|------------------------------------|
| Level | 0 <input checked="" type="radio"/> |
|-------|------------------------------------|

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|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

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|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1941_05_00RU.JPG |
|-------------------|-------------------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 23 JUN 2014 |
|---------------------------------|-------------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (6)**

**Generated On: 20 Jul 2016 16:57:04**

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1941 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 06 |
|--------------------------|----|

---

|       |                                    |
|-------|------------------------------------|
| Level | 0 <input checked="" type="radio"/> |
|-------|------------------------------------|

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|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

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|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1941_06_1WHU.JPG |
|-------------------|-------------------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 23 JUN 2014 |
|---------------------------------|-------------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (7)**

**Generated On: 20 Jul 2016 16:57:04**

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1941 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 07 |
|--------------------------|----|

---

|       |                         |
|-------|-------------------------|
| Level | 0 <input type="radio"/> |
|-------|-------------------------|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1941_07_6PR5.JPG |
|-------------------|-------------------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 23 JUN 2014 |
|---------------------------------|-------------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (8)**

**Generated On: 20 Jul 2016 16:57:04**

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1941 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 08 |
|--------------------------|----|

---

|       |   |
|-------|---|
| Level | 0  |
|-------|---|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1941_08_AKSI.JPG |
|-------------------|-------------------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 23 JUN 2014 |
|---------------------------------|-------------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (9)**

**Generated On: 20 Jul 2016 16:57:04**

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1941 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 09 |
|--------------------------|----|

---

|       |                                    |
|-------|------------------------------------|
| Level | 0 <input checked="" type="radio"/> |
|-------|------------------------------------|

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|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

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|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1941_09_2XSB.JPG |
|-------------------|-------------------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 23 JUN 2014 |
|---------------------------------|-------------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (10)**

**Generated On: 20 Jul 2016 16:57:04**

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1941 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 10 |
|--------------------------|----|

---

|       |                         |
|-------|-------------------------|
| Level | 0 <input type="radio"/> |
|-------|-------------------------|

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|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

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|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1941_10_3RR4.JPG |
|-------------------|-------------------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 23 JUN 2014 |
|---------------------------------|-------------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (11)**

**Generated On: 20 Jul 2016 16:57:04**

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1941 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 11 |
|--------------------------|----|

---

|       |   |
|-------|---|
| Level | 0  |
|-------|---|

---

|             |       |
|-------------|-------|
| Observation | <hr/> |
|-------------|-------|

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|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1941_11_OLSP.JPG |
|-------------------|-------------------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 23 JUN 2014 |
|---------------------------------|-------------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (12)**

**Generated On: 20 Jul 2016 16:57:04**

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|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1941 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 12 |
|--------------------------|----|

---

|       |                         |
|-------|-------------------------|
| Level | 0 <input type="radio"/> |
|-------|-------------------------|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

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|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1941_12_23ML.JPG |
|-------------------|-------------------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 23 JUN 2014 |
|---------------------------------|-------------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (13)**

**Generated On: 20 Jul 2016 16:57:04**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1941 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 13 |
|--------------------------|----|

---

|       |                         |
|-------|-------------------------|
| Level | 0 <input type="radio"/> |
|-------|-------------------------|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

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|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1941_13_6RSZ.JPG |
|-------------------|-------------------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 23 JUN 2014 |
|---------------------------------|-------------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (1)**

**Generated On: 20 Jul 2016 16:57:04**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1943 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 01 |
|--------------------------|----|

---

|       |                                    |
|-------|------------------------------------|
| Level | 0 <input checked="" type="radio"/> |
|-------|------------------------------------|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

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|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1943_01_AVU3.JPG |
|-------------------|-------------------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 23 JUN 2014 |
|---------------------------------|-------------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (2)**

**Generated On: 20 Jul 2016 16:57:04**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1943 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 02 |
|--------------------------|----|

---

|       |                                    |
|-------|------------------------------------|
| Level | 0 <input checked="" type="radio"/> |
|-------|------------------------------------|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1943_02_3B0D.JPG |
|-------------------|-------------------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 23 JUN 2014 |
|---------------------------------|-------------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (3)**

**Generated On: 20 Jul 2016 16:57:04**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1943 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 03 |
|--------------------------|----|

---

|       |                                    |
|-------|------------------------------------|
| Level | 0 <input checked="" type="radio"/> |
|-------|------------------------------------|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1943_03_0X8N.JPG |
|-------------------|-------------------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 23 JUN 2014 |
|---------------------------------|-------------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (4)**

**Generated On: 20 Jul 2016 16:57:04**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1943 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 04 |
|--------------------------|----|

---

|       |   |
|-------|---|
| Level | 0  |
|-------|---|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1943_04_SAEQ.JPG |
|-------------------|-------------------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 23 JUN 2014 |
|---------------------------------|-------------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (5)**

**Generated On: 20 Jul 2016 16:57:04**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1943 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 05 |
|--------------------------|----|

---

|       |                                    |
|-------|------------------------------------|
| Level | 0 <input checked="" type="radio"/> |
|-------|------------------------------------|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

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|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1943_05_4UEZ.JPG |
|-------------------|-------------------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 23 JUN 2014 |
|---------------------------------|-------------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (6)**

**Generated On: 20 Jul 2016 16:57:04**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1943 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 06 |
|--------------------------|----|

---

|       |   |
|-------|---|
| Level | 0  |
|-------|---|

---

|             |       |
|-------------|-------|
| Observation | <hr/> |
|-------------|-------|

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|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1943_06_QWVZ.JPG |
|-------------------|-------------------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 23 JUN 2014 |
|---------------------------------|-------------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (7)**

**Generated On: 20 Jul 2016 16:57:04**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1943 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 07 |
|--------------------------|----|

---

|       |                                    |
|-------|------------------------------------|
| Level | 0 <input checked="" type="radio"/> |
|-------|------------------------------------|

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|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

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|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1943_07_3WQ1.JPG |
|-------------------|-------------------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 23 JUN 2014 |
|---------------------------------|-------------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (8)**

**Generated On: 20 Jul 2016 16:57:04**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1943 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 08 |
|--------------------------|----|

---

|       |                                    |
|-------|------------------------------------|
| Level | 0 <input checked="" type="radio"/> |
|-------|------------------------------------|

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|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

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|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1943_08_O5AN.JPG |
|-------------------|-------------------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 23 JUN 2014 |
|---------------------------------|-------------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (9)**

**Generated On: 20 Jul 2016 16:57:04**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1943 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 09 |
|--------------------------|----|

---

|       |                                    |
|-------|------------------------------------|
| Level | 0 <input checked="" type="radio"/> |
|-------|------------------------------------|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1943_09_Y7PZ.JPG |
|-------------------|-------------------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 23 JUN 2014 |
|---------------------------------|-------------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (1)**

**Generated On: 20 Jul 2016 16:57:04**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1949 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 01 |
|--------------------------|----|

---

|       |                                    |
|-------|------------------------------------|
| Level | 0 <input checked="" type="radio"/> |
|-------|------------------------------------|

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|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1949_01_FP02.JPG |
|-------------------|-------------------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 23 JUN 2014 |
|---------------------------------|-------------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (2)**

**Generated On: 20 Jul 2016 16:57:04**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1949 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 02 |
|--------------------------|----|

---

|       |                                    |
|-------|------------------------------------|
| Level | 0 <input checked="" type="radio"/> |
|-------|------------------------------------|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1949_02_OEYB.JPG |
|-------------------|-------------------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 23 JUN 2014 |
|---------------------------------|-------------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (3)**

**Generated On: 20 Jul 2016 16:57:04**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1949 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 03 |
|--------------------------|----|

---

|       |                                    |
|-------|------------------------------------|
| Level | 0 <input checked="" type="radio"/> |
|-------|------------------------------------|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1949_03_2DRW.JPG |
|-------------------|-------------------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 23 JUN 2014 |
|---------------------------------|-------------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (4)**

**Generated On: 20 Jul 2016 16:57:04**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1949 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 04 |
|--------------------------|----|

---

|       |   |
|-------|---|
| Level | 0  |
|-------|---|

---

|             |       |
|-------------|-------|
| Observation | <hr/> |
|-------------|-------|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1949_04_SOOS.JPG |
|-------------------|-------------------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 23 JUN 2014 |
|---------------------------------|-------------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (5)**

**Generated On: 20 Jul 2016 16:57:04**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1949 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 05 |
|--------------------------|----|

---

|       |                                    |
|-------|------------------------------------|
| Level | 0 <input checked="" type="radio"/> |
|-------|------------------------------------|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1949_05_LX43.JPG |
|-------------------|-------------------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 23 JUN 2014 |
|---------------------------------|-------------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (6)**

**Generated On: 20 Jul 2016 16:57:04**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1949 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 06 |
|--------------------------|----|

---

|       |                                    |
|-------|------------------------------------|
| Level | 0 <input checked="" type="radio"/> |
|-------|------------------------------------|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1949_06_0SFR.JPG |
|-------------------|-------------------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 23 JUN 2014 |
|---------------------------------|-------------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (7)**

**Generated On: 20 Jul 2016 16:57:04**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1949 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 07 |
|--------------------------|----|

---

|       |                                    |
|-------|------------------------------------|
| Level | 0 <input checked="" type="radio"/> |
|-------|------------------------------------|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1949_07_13RJ.JPG |
|-------------------|-------------------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 23 JUN 2014 |
|---------------------------------|-------------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (8)**

**Generated On: 20 Jul 2016 16:57:04**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1949 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 08 |
|--------------------------|----|

---

|       |                                    |
|-------|------------------------------------|
| Level | 0 <input checked="" type="radio"/> |
|-------|------------------------------------|

---

|             |  |
|-------------|--|
| Observation |  |
|-------------|--|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1949_08_LIE3.JPG |
|-------------------|-------------------|

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|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 23 JUN 2014 |
|---------------------------------|-------------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Visual Inspection of the Tobacco Plugs Results for THS (9)**

**Generated On: 20 Jul 2016 16:57:04**

---

|                         |       |
|-------------------------|-------|
| Tobacco plug kit number | T1949 |
|-------------------------|-------|

---

|                          |    |
|--------------------------|----|
| Tobacco plug vial number | 09 |
|--------------------------|----|

---

|       |   |
|-------|---|
| Level | 0  |
|-------|---|

---

|             |       |
|-------------|-------|
| Observation | <hr/> |
|-------------|-------|

---

|                   |                   |
|-------------------|-------------------|
| Picture File Name | T1949_09_BNGR.JPG |
|-------------------|-------------------|

---

|                                 |             |
|---------------------------------|-------------|
| Date of analysis<br>DD/MMM/YYYY | 23 JUN 2014 |
|---------------------------------|-------------|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Product use diary(Paper)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:55**

**Generated On: 20 Jul 2016 16:57:04**

---

Was paper questionnaire used?

No ☒

---

Reason not done

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Product use diary(Paper) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:55**

**Generated On: 20 Jul 2016 16:57:04**

---

Was paper questionnaire used?

No ☐

---

Reason not done

---

Date of completion  
DD/MMM/YYYY

---

Time of completion  
hh:mm

---

Date the questionnaire was completed for  
DD/MMM/YYYY

---

What tobacco/nicotine product did you use today?

---

How many THS 2.2 tobacco sticks did you use today?

---

How many CC/ roll-your-own did you smoke today?

---

What NRT product did you used today?

---

How many times did you use an inhaler today?

---

How many times did you use a nasal spray today?

---

How many gums did you use today?

---

How many lozenges did you use today?

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Product Use**

**Form: Product use diary(Paper) (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:55**

**Generated On: 20 Jul 2016 16:57:04**

---

How many patches did you use today? \_\_\_\_\_

---

How many times did you use other NRT products today  
not listed previously? \_\_\_\_\_

---

What other tobacco product did you used today? \_\_\_\_\_

---

How many times did you use chewable/smokeless  
tobacco today? \_\_\_\_\_

---

How many cigars/cigarillos did you smoke today? \_\_\_\_\_

---

How many times did you smoke a pipe today? \_\_\_\_\_

---

How many times did you use a tobacco product today  
not listed previously? \_\_\_\_\_

---

How many times did you use an electronic cigarette  
today? \_\_\_\_\_

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Adverse Events**

**Form: Adverse Events Y/N**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:55**

**Generated On: 20 Jul 2016 16:57:04**

---

Was there any Adverse Event for this subject?

No ☒

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Previous and Concomitant Medication**

**Form: Previous and Concomitant Medication Y/N**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:55**

**Generated On: 20 Jul 2016 16:57:04**

---

Has the subject taken previous or concomitant  
medication?

---

No ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Device Inventory**

**Form: Device Inventory - THS 2.2 menthol Cigarette Holder (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:55**

**Generated On: 20 Jul 2016 16:57:04**

---

|                  |   |
|------------------|---|
| Device Inventory | 1 |
| Log Number       |   |

---

|                             |             |
|-----------------------------|-------------|
| Date of Device Distribution | 09 MAR 2014 |
| DD/MMM/YYYY                 |             |

---

|                        |       |
|------------------------|-------|
| Time of                | 06:56 |
| Device Distribution    |       |
| hour:min 24-hour clock |       |

---

|             |                          |
|-------------|--------------------------|
| Device Type | THS 2.2 CIGARETTE HOLDER |
|-------------|--------------------------|

---

|                      |         |
|----------------------|---------|
| Device Serial Number | 1245489 |
|----------------------|---------|

---

|                           |             |
|---------------------------|-------------|
| Date of Device Collection | 14 MAR 2014 |
| DD/MMM/YYYY               |             |

---

|                        |       |
|------------------------|-------|
| Time of                | 10:22 |
| Device Collection      |       |
| hour:min 24-hour clock |       |

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Device Inventory**

**Form: Device Inventory - THS 2.2 menthol Cigarette Holder (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:55**

**Generated On: 20 Jul 2016 16:57:04**

---

|                  |   |
|------------------|---|
| Device Inventory | 2 |
| Log Number       |   |

---

|                             |             |
|-----------------------------|-------------|
| Date of Device Distribution | 09 MAR 2014 |
| DD/MMM/YYYY                 |             |

---

|                        |       |
|------------------------|-------|
| Time of                | 06:56 |
| Device Distribution    |       |
| hour:min 24-hour clock |       |

---

|             |                          |
|-------------|--------------------------|
| Device Type | THS 2.2 CIGARETTE HOLDER |
|-------------|--------------------------|

---

|                      |         |
|----------------------|---------|
| Device Serial Number | 1249239 |
|----------------------|---------|

---

|                           |             |
|---------------------------|-------------|
| Date of Device Collection | 14 MAR 2014 |
| DD/MMM/YYYY               |             |

---

|                        |       |
|------------------------|-------|
| Time of                | 10:22 |
| Device Collection      |       |
| hour:min 24-hour clock |       |

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Folder: Device Inventory**

**Form: Device Inventory - THS 2.2 menthol Charging Unit (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:35:55**

**Generated On: 20 Jul 2016 16:57:04**

---

|                  |   |
|------------------|---|
| Device Inventory | 1 |
| Log Number       |   |

---

|                             |             |
|-----------------------------|-------------|
| Date of Device Distribution | 09 MAR 2014 |
| DD/MMM/YYYY                 |             |

---

|                        |       |
|------------------------|-------|
| Time of                | 06:56 |
| Device Distribution    |       |
| hour:min 24-hour clock |       |

---

|             |                       |
|-------------|-----------------------|
| Device Type | THS 2.2 CHARGING UNIT |
|-------------|-----------------------|

---

|                      |         |
|----------------------|---------|
| Device Serial Number | 1318185 |
|----------------------|---------|

---

|                           |             |
|---------------------------|-------------|
| Date of Device Collection | 14 MAR 2014 |
| DD/MMM/YYYY               |             |

---

|                        |       |
|------------------------|-------|
| Time of                | 10:22 |
| Device Collection      |       |
| hour:min 24-hour clock |       |

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Form: Product use diary (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

|   |   |
|---|---|
| Date of Birth   | (b) (6)   |
| Date of completion<br>DD/MMM/YYYY                       | 2014 MAR 15                                     |
| Time of completion<br>hh:mm                             | 06:11   |
| Date the questionnaire was completed for<br>DD/MMM/YYYY | 2014 MAR 14                                     |
| 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?      | 7   |
| 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: 1194**

**Form: Product use diary (1)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

---

|                                     |    |
|-------------------------------------|----|
| 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: 1194**

**Form: Product use diary (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

|   |   |
|---|---|
| Date of Birth   | (b) (6)   |
| Date of completion<br>DD/MMM/YYYY                       | 2014 MAR 15                                     |
| Time of completion<br>hh:mm                             | 20:01   |
| Date the questionnaire was completed for<br>DD/MMM/YYYY | 2014 MAR 15                                     |
| 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: 1194**

**Form: Product use diary (2)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

---

|                                     |    |
|-------------------------------------|----|
| 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: 1194**

**Form: Product use diary (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

|   |   |
|---|---|
| Date of Birth   | (b) (6)   |
| Date of completion<br>DD/MMM/YYYY                       | 2014 MAR 16                                     |
| Time of completion<br>hh:mm                             | 20:00   |
| Date the questionnaire was completed for<br>DD/MMM/YYYY | 2014 MAR 16                                     |
| 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?      | 10  |
| 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: 1194**

**Form: Product use diary (3)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

---

|                                     |    |
|-------------------------------------|----|
| 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: 1194**

**Form: Product use diary (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

---

Date of Birth

(b) (6)

---

Date of completion  
DD/MMM/YYYY

2014 MAR 17

---

Time of completion  
hh:mm

20:01

---

Date the questionnaire was completed for  
DD/MMM/YYYY

2014 MAR 17

---

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?

12

---

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: 1194**

**Form: Product use diary (4)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

---

|                                     |    |
|-------------------------------------|----|
| 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: 1194**

**Form: Product use diary (5)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

|   |   |
|---|---|
| Date of Birth   | (b) (6)   |
| Date of completion<br>DD/MMM/YYYY                       | 2014 MAR 18                                     |
| Time of completion<br>hh:mm                             | 20:06   |
| Date the questionnaire was completed for<br>DD/MMM/YYYY | 2014 MAR 18                                     |
| 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?      | 7   |
| 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: 1194**

**Form: Product use diary (5)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

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|                                     |    |
|-------------------------------------|----|
| 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 |
|---|----|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,  
Florida: 1194**

**Form: Product use diary (6)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

|   |   |
|---|---|
| Date of Birth   | (b) (6)   |
| Date of completion<br>DD/MMM/YYYY                       | 2014 MAR 20                                     |
| Time of completion<br>hh:mm                             | 11:00   |
| Date the questionnaire was completed for<br>DD/MMM/YYYY | 2014 MAR 19                                     |
| 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: 1194**

**Form: Product use diary (6)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

---

|                                     |    |
|-------------------------------------|----|
| 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: 1194**

**Form: Product use diary (7)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

---

Date of Birth

(b) (6)

---

Date of completion  
DD/MMM/YYYY

2014 MAR 20

---

Time of completion  
hh:mm

20:00

---

Date the questionnaire was completed for  
DD/MMM/YYYY

2014 MAR 20

---

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?

10

---

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: 1194**

**Form: Product use diary (7)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

---

|                                     |    |
|-------------------------------------|----|
| How many patches did you use today? | -9 |
|-------------------------------------|----|

---

|   |    |
|---|----|
| How many times did you use other NRT products today<br>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<br>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<br>not listed previously? | -9 |
|--|----|

---

|  |    |
|--|----|
| How many times did you use an electronic cigarette<br>today? | -9 |
|--|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Form: Product use diary (8)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

|   |   |
|---|---|
| Date of Birth   | (b) (6)   |
| Date of completion<br>DD/MMM/YYYY                       | 2014 MAR 22                                     |
| Time of completion<br>hh:mm                             | 20:24   |
| Date the questionnaire was completed for<br>DD/MMM/YYYY | 2014 MAR 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?      | 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: 1194**

**Form: Product use diary (8)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

---

|                                     |    |
|-------------------------------------|----|
| 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: 1194**

**Form: Product use diary (9)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

---

Date of Birth

(b) (6)

---

Date of completion  
DD/MMM/YYYY

2014 MAR 23

---

Time of completion  
hh:mm

20:06

---

Date the questionnaire was completed for  
DD/MMM/YYYY

2014 MAR 23

---

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?

10

---

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: 1194**

**Form: Product use diary (9)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

---

|                                     |    |
|-------------------------------------|----|
| 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: 1194**

**Form: Product use diary (10)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

---

Date of Birth

(b) (6)

---

Date of completion  
DD/MMM/YYYY

2014 MAR 24

---

Time of completion  
hh:mm

23:04

---

Date the questionnaire was completed for  
DD/MMM/YYYY

2014 MAR 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?

11

---

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: 1194**

**Form: Product use diary (10)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

---

|                                     |    |
|-------------------------------------|----|
| How many patches did you use today? | -9 |
|-------------------------------------|----|

---

|   |    |
|---|----|
| How many times did you use other NRT products today<br>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<br>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<br>not listed previously? | -9 |
|--|----|

---

|  |    |
|--|----|
| How many times did you use an electronic cigarette<br>today? | -9 |
|--|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Form: Product use diary (11)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

---

Date of Birth

(b) (6)

---

Date of completion  
DD/MMM/YYYY

2014 MAR 25

---

Time of completion  
hh:mm

23:01

---

Date the questionnaire was completed for  
DD/MMM/YYYY

2014 MAR 25

---

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?

11

---

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: 1194**

**Form: Product use diary (11)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

---

|                                     |    |
|-------------------------------------|----|
| 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: 1194**

**Form: Product use diary (12)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

---

Date of Birth

(b) (6)

---

Date of completion  
DD/MMM/YYYY

2014 MAR 26

---

Time of completion  
hh:mm

21:00

---

Date the questionnaire was completed for  
DD/MMM/YYYY

2014 MAR 26

---

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: 1194**

**Form: Product use diary (12)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

---

|                                     |    |
|-------------------------------------|----|
| 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: 1194**

**Form: Product use diary (13)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

---

Date of Birth

(b) (6)

---

Date of completion  
DD/MMM/YYYY

2014 MAR 27

---

Time of completion  
hh:mm

23:20

---

Date the questionnaire was completed for  
DD/MMM/YYYY

2014 MAR 27

---

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?

13

---

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: 1194**

**Form: Product use diary (13)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

---

|                                     |    |
|-------------------------------------|----|
| 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: 1194**

**Form: Product use diary (14)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

|   |   |
|---|---|
| Date of Birth   | (b) (6)   |
| Date of completion<br>DD/MMM/YYYY                       | 2014 MAR 28                                     |
| Time of completion<br>hh:mm                             | 20:20   |
| Date the questionnaire was completed for<br>DD/MMM/YYYY | 2014 MAR 28                                     |
| 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?      | 12  |
| 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: 1194**

**Form: Product use diary (14)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

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|                                     |    |
|-------------------------------------|----|
| 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: 1194**

**Form: Product use diary (15)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

---

Date of Birth

(b) (6)

---

Date of completion  
DD/MMM/YYYY

2014 MAR 29

---

Time of completion  
hh:mm

23:06

---

Date the questionnaire was completed for  
DD/MMM/YYYY

2014 MAR 29

---

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?

13

---

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: 1194**

**Form: Product use diary (15)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

---

|                                     |    |
|-------------------------------------|----|
| How many patches did you use today? | -9 |
|-------------------------------------|----|

---

|   |    |
|---|----|
| How many times did you use other NRT products today<br>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<br>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<br>not listed previously? | -9 |
|--|----|

---

|  |    |
|--|----|
| How many times did you use an electronic cigarette<br>today? | -9 |
|--|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Form: Product use diary (16)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

|   |   |
|---|---|
| Date of Birth   | (b) (6)   |
| Date of completion<br>DD/MMM/YYYY                       | 2014 MAR 30                                     |
| Time of completion<br>hh:mm                             | 19:59   |
| Date the questionnaire was completed for<br>DD/MMM/YYYY | 2014 MAR 30                                     |
| 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: 1194**

**Form: Product use diary (16)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

---

|                                     |    |
|-------------------------------------|----|
| 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: 1194**

**Form: Product use diary (17)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

---

Date of Birth

(b) (6)

---

Date of completion  
DD/MMM/YYYY

2014 MAR 31

---

Time of completion  
hh:mm

19:28

---

Date the questionnaire was completed for  
DD/MMM/YYYY

2014 MAR 31

---

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?

11

---

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: 1194**

**Form: Product use diary (17)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

---

|                                     |    |
|-------------------------------------|----|
| 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: 1194**

**Form: Product use diary (18)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

---

Date of Birth

(b) (6)

---

Date of completion  
DD/MMM/YYYY

2014 APR 01

---

Time of completion  
hh:mm

22:01

---

Date the questionnaire was completed for  
DD/MMM/YYYY

2014 APR 01

---

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?

10

---

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: 1194**

**Form: Product use diary (18)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

---

|                                     |    |
|-------------------------------------|----|
| 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: 1194**

**Form: Product use diary (19)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

---

Date of Birth

(b) (6)

---

Date of completion  
DD/MMM/YYYY

2014 APR 03

---

Time of completion  
hh:mm

08:31

---

Date the questionnaire was completed for  
DD/MMM/YYYY

2014 APR 02

---

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: 1194**

**Form: Product use diary (19)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

---

|                                     |    |
|-------------------------------------|----|
| 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: 1194**

**Form: Product use diary (20)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

---

Date of Birth

(b) (6)

---

Date of completion  
DD/MMM/YYYY

2014 APR 03

---

Time of completion  
hh:mm

19:27

---

Date the questionnaire was completed for  
DD/MMM/YYYY

2014 APR 03

---

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?

13

---

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: 1194**

**Form: Product use diary (20)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

---

|                                     |    |
|-------------------------------------|----|
| 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: 1194**

**Form: Product use diary (21)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

---

Date of Birth

(b) (6)

---

Date of completion  
DD/MMM/YYYY

2014 APR 04

---

Time of completion  
hh:mm

20:00

---

Date the questionnaire was completed for  
DD/MMM/YYYY

2014 APR 04

---

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?

13

---

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: 1194**

**Form: Product use diary (21)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

---

|                                     |    |
|-------------------------------------|----|
| 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: 1194**

**Form: Product use diary (22)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

---

Date of Birth

(b) (6)

---

Date of completion  
DD/MMM/YYYY

2014 APR 05

---

Time of completion  
hh:mm

23:00

---

Date the questionnaire was completed for  
DD/MMM/YYYY

2014 APR 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?

15

---

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: 1194**

**Form: Product use diary (22)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

---

|                                     |    |
|-------------------------------------|----|
| How many patches did you use today? | -9 |
|-------------------------------------|----|

---

|   |    |
|---|----|
| How many times did you use other NRT products today<br>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<br>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<br>not listed previously? | -9 |
|--|----|

---

|  |    |
|--|----|
| How many times did you use an electronic cigarette<br>today? | -9 |
|--|----|

---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Form: Product use diary (23)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

---

Date of Birth

(b) (6)

---

Date of completion  
DD/MMM/YYYY

2014 APR 06

---

Time of completion  
hh:mm

20:00

---

Date the questionnaire was completed for  
DD/MMM/YYYY

2014 APR 06

---

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?

12

---

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: 1194**

**Form: Product use diary (23)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

---

|                                     |    |
|-------------------------------------|----|
| 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: 1194**

**Form: Product use diary (24)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

---

Date of Birth

(b) (6)

---

Date of completion  
DD/MMM/YYYY

2014 APR 07

---

Time of completion  
hh:mm

21:00

---

Date the questionnaire was completed for  
DD/MMM/YYYY

2014 APR 07

---

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?

13

---

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: 1194**

**Form: Product use diary (24)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

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|                                     |    |
|-------------------------------------|----|
| 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: 1194**

**Form: Product use diary (25)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

---

Date of Birth

(b) (6)

---

Date of completion  
DD/MMM/YYYY

2014 APR 08

---

Time of completion  
hh:mm

20:00

---

Date the questionnaire was completed for  
DD/MMM/YYYY

2014 APR 08

---

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?

12

---

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: 1194**

**Form: Product use diary (25)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

---

|                                     |    |
|-------------------------------------|----|
| 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: 1194**

**Form: Product use diary (26)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

---

Date of Birth

(b) (6)

---

Date of completion  
DD/MMM/YYYY

2014 APR 09

---

Time of completion  
hh:mm

20:01

---

Date the questionnaire was completed for  
DD/MMM/YYYY

2014 APR 09

---

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: 1194**

**Form: Product use diary (26)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

---

|                                     |    |
|-------------------------------------|----|
| 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: 1194**

**Form: Product use diary (27)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

---

Date of Birth

(b) (6)

---

Date of completion  
DD/MMM/YYYY

2014 APR 10

---

Time of completion  
hh:mm

21:00

---

Date the questionnaire was completed for  
DD/MMM/YYYY

2014 APR 10

---

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?

6

---

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: 1194**

**Form: Product use diary (27)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

---

|                                     |    |
|-------------------------------------|----|
| 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 |
|---|----|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Form: Product use diary (28)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

|   |   |
|---|---|
| Date of Birth   | (b) (6)   |
| Date of completion<br>DD/MMM/YYYY                       | 2014 APR 11                                     |
| Time of completion<br>hh:mm                             | 21:00   |
| Date the questionnaire was completed for<br>DD/MMM/YYYY | 2014 APR 11                                     |
| 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?      | 7   |
| 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: 1194**

**Form: Product use diary (28)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

---

|                                     |    |
|-------------------------------------|----|
| 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 |
|---|----|

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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Form: Product use diary (29)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

---

Date of Birth

(b) (6)

---

Date of completion  
DD/MMM/YYYY

2014 APR 12

---

Time of completion  
hh:mm

20:00

---

Date the questionnaire was completed for  
DD/MMM/YYYY

2014 APR 12

---

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?

4

---

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: 1194**

**Form: Product use diary (29)**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:54**

**Generated On: 20 Jul 2016 16:57:04**

---

|                                     |    |
|-------------------------------------|----|
| 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: 1194**

**Form: End of study**

**Data signed: (hcoleman1) 18 Jun 2015 20:59:09**

**Generated On: 20 Jul 2016 16:57:04**

---

End of study date

12 APR 2014  
DD/MMM/YYYY

---

Has the subject completed the study ?

No ☒

---

If No, please specify the reason:

Lost To Follow-up ☒

---

Details:

---



**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1194**

**Form: Consent Withdrawal**

**Data signed: (hfarmer1) 27 Mar 2015 14:33:53**

**Generated On: 20 Jul 2016 16:57:04**

---

Did the subject withdraw it's consent to the biobanking  
for BoExp and risk markers?

No ☒

---

Date of withdrawal of consent for biobanking for BoEXP  
and risk markers

---

---

Did the subject withdraw it's consent to the  
transcriptomics analysis?

No ☒

---

Date of withdrawal of consent for transcriptomics  
analysis

---